Thesis Project Portfolio

SpellCheck: An Educational Device to Improve Children's Spelling

(Technical Report)

FDA Regulation of Artificial Intelligence in Medical Software

(STS Research Paper)

An Undergraduate Thesis

Presented to the Faculty of the School of Engineering and Applied Science

University of Virginia • Charlottesville, Virginia

In Fulfillment of the Requirements for the Degree

Bachelor of Science, School of Engineering

Noah Beamon

Spring, 2022

Department of Electrical and Computer Engineering

Table of Contents

Sociotechnical Synthesis

This portfolio consists of two projects. A technical report and a Science Technology and Society (STS) research paper. The technical report contains the design, development, and demonstration of a children's spelling device to understand how game-based learning impacts children's ability to learn how to spell English words. The STS research paper employs actor network theory (ANT) to address the Food and Drug Administration (FDA) regulatory framework of artificial intelligence (AI) and machine learning (ML) in medical devices and medical software to explain the continuity of the use of computer aided diagnosis (CAD) software in medicine. Although these projects are unrelated, they comprehensively address regulatory implications and the issue of product affordability. I learned that all industries employing technology must successfully manage regulatory and affordability challenges.

The first concept that is applicable to both projects is the consideration of regulatory implications. Children's educational devices and medical software applications are both bureaucratically regulated in the U.S. The advancements made within these industries and the progress of these industries comprehensively rely on bureaucratic regulatory frameworks. These regulatory frameworks coincidentally facilitate the continuity of these industries through restrictive and expansive measures which ensure safety and efficacy. In *Revealed Bureaucratic Preference: Priorities of the Consumer Product Safety Commission*, Thomas states, "the Consumer Product Safety Commission (CPSC) is empowered to reduce or to eliminate consumer exposure to unreasonable hazards from every consumer product not elsewhere regulated by the U.S government" (Thomas). In the development of the children's spelling device, a combination of U.S regulations and international standards was paramount for ensuring the production of the device met physical safety standards including the CPSC standard 16 CFR addressing the safety

of child toys and the IPC standards for printed circuit board (PCB) design. In *Software As a Medical Device: FDA Digital Health Regulation*, Deloitte states, "In mid-2017 the FDA release[ed] three new guidance documents—two of which distinguish between device types that are low-risk and, therefore, no longer required to undergo pre-market review, and one which outlines new guidelines for evaluating [Software as a Medical Device (SaMD)] applications" (Deloitte). The FDA designates CAD software as SaMD and encourages CAD software engineers to adhere to a set of established standards when integrating AI and ML in CAD software. Both projects involve regulatory implications that influence product development.

The second concept that is applicable to both projects is affordability. Child educational devices and medical software must be affordable and effective, so all individuals have access to the benefits the technology provides. In *Realizing the promise: How can education technology improve learning for all?*, Ganimain asks the following questions when discussing electronic white boards: "Will these expensive boards be used in the same way as the old chalkboards? Will providing one device (laptop or tablet) to each learner facilitate access to more and better content, or offer students more opportunities to practice and learn?" (Ganimain). Similar inquiries must be considered for the children's spelling device; engineers must consider whether the device makes an impact and whether it will be accessible to everyone based on its price. In *Who Will Pay for AI?*, Chen states, "Development of artificial intelligence (AI) in radiology has been much more rapid than in other specialties in health care. . .U.S. regulatory approval is the initial hurdle for adoption of AI in the United States. A much bigger hurdle for broader adoption of new technology is payment" (Chen). Although the first challenge to implementing software into health care is establishing a regulatory framework, establishing an insurance policy to pay

for it and make it accessible to everyone is also a challenge. Both projects involve devices for which affordability is a factor of consideration.

References

Chen, M. M., Golding, L. P., & Nicola, G. N. (2021). Who Will Pay for AI? *Radiology: Artificial Intelligence*, *3*(3), e210030. https://doi.org/10.1148/ryai.2021210030

Realizing the promise: How can education technology improve learning for all? (2020, September 10). *Brookings*. https://www.brookings.edu/essay/realizing-the-promise-how-can-education-technology-improve-learning-for-all/

Software As a Medical Device: FDA Digital Health Regulation. (n.d.). Deloitte United States. Retrieved April 11, 2022, from https://www2.deloitte.com/us/en/pages/public-sector/articles/software-as-a-medical-device-fda.html

Thomas, L. G. (1988). Revealed Bureaucratic Preference: Priorities of the Consumer Product Safety Commission. *The RAND Journal of Economics*, *19*(1), 102–113. https://doi.org/10.2307/2555400

SpellCheck: An Educational Device to Improve Children's Spelling

A Technical Report submitted to the Department of Electrical and Computer Engineering

Presented to the Faculty of the School of Engineering and Applied Science

University of Virginia • Charlottesville, Virginia

In Partial Fulfillment of the Requirements for the Degree

Bachelor of Science, School of Engineering

Noah Beamon

Spring, 2022

Technical Project Team Members

Noah Beamon

Justin Guo

Rachel Lew

Catlinh Nguyen

Shymbolat Tnaliyev

On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

Harry Powell, Department of Electrical and Computer Engineering

SpellCheck: An Educational Device to Improve Children's Spelling

Banana Seals/SpellCheck

Noah Beamon, Justin Guo, Rachel Lew, Catlinh Nguyen, Shymbolat Tnaliyev

December 15, 2021

Capstone Design ECE 4440 / ECE4991

Signatures

Noah Beamon

Justin Guo

Rachel Lew

CNguyen

Shymbolat Tnaliyev

Statement of work:

Noah Beamon:

My main responsibility was LCD communication involving the transfer of words and images from the web application to the MSP432 itself for display on the LCD. This role consisted of two main parts: the first was writing Embedded C code for the reception of data over backchannel UART on the MSP432 and the second was the development of the web application functionality of sending multiple words and images from a dynamic user interface. For the Embedded C microcontroller code, I used an interrupt service routine (ISR), circular buffer, ACK, and memory allocation logic to receive and process the data from the PC host. For the web application code, I used Javascript with React library to develop a user interface that allows the user to enter and send custom words and images to the device in addition to default words and images. In addition to Javascript code written to control the UI, this process mainly involved using an image resizing library to dynamically resize the images to maintain aspect ratio and a standard of quality. My secondary responsibility was assisting in the development and analysis of the power supply and the barrel jack custom footprint.

Justin Guo:

My main responsibility was coding the software concerning the interaction between the LCD and the MSP432. I configured SPI communication between the two, allowing the MSP to send commands to the LCD. Using these commands, I was able to toggle the LCD's power state, display pictures, toggle between different text, and draw buttons. I also made the decoding algorithm for the multiplexer inputs into the ADC of the MSP, which was then drawn onto the LCD as a string. I also saved the user inputted images in flash, allowing the system to continue playing. Finally, I also helped design the game of the project, which involved a touch button as verification and repeated checks on input.

My secondary responsibility was building the design for the letter verification system. I helped verify correct connections between the hall effect sensors and multiplexers, and I designed the software algorithm to read to the multiplexers using the ADCs.

Rachel Lew:

My primary responsibility was to design the mechanical aspect of the system. I chose the chassis and mounting appliances for the system and created the CAD designs for the 3D printed slot panel and letter blocks using Autodesk Fusion 360. I also assembled the system, which includes placing the magnets into the letter blocks in the correct combinations, mounting the PCB and slot panel, and mounting the LCD.

I had to closely work with Catlinh to ensure my 3D designs would sync with the letter identification system, so I was involved with the letter identification design. I helped with the magnet sensing testing to ensure my designs for the letter blocks and panel were workable. I also worked with Catlinh on the PCB to ensure that the PCB could align with the 3D printed panel. I determined the dimensions necessary for the PCB and the placement for certain components to work best with the chassis and helped route the board for manufacturing.

Catlinh Nguyen:

My primary responsibility was to design the letter identification system. I researched the components and determined the magnet strength and sensor sensitivity that would be sufficient for our system. I performed extensive testing to ensure that the Hall Effect sensor and magnet system would allow us to accurately identify which letters were placed in the slots. Furthermore, I had to work closely with Rachel to ensure that the letter identification system placement would match the dimensions for the enclosure and 3D printed panel.

My secondary responsibility was to work with Rachel to design the system schematic and board layout. I configured the letter identification system that I designed in Multisim and made the connections that would allow us to power our system using the power supply circuit and interface our system with the MSP432 microcontroller and the LCD connector. Once the schematic was completed, Rachel and I worked together to route the board for manufacturing and assemble the PCB within the system.

Shymbolat Tnaliyev:

My primary task was power supply involving the power requirements for our LCD display and researching the suitable voltage regulator for our system. After analysis and the professor's recommendation, the R-783.305 with 3.3V output voltage and 0.5A current output voltage regulator was chosen.Then I completed the task which required us to find the right wall transformer so that it would satisfy our given requirements using all components' current measurements for the system. Finally, the barrel jack component research was done, and it was chosen respectively.

My secondary task was to help Noah with LCD communication involving the user web site for downloading and sending words for the device. I worked and assisted with UI for clients of our website and making technical support pages. I created end-user documentation to guide the users on how to properly install and use the product.

Table of Contents

Contents

Table of Figures

Table of Tables

Abstract

SpellCheck is an educational device which facilitates learning in youth ages 5 to 7. Specifically, this interactive educational tool will help children practice how to spell the name of an object that appears on a screen. The device displays an image of an object on the LCD, the child places individual letters into their respective slots in the device, and the spelling is verified through the arrangement of letters in the slots. LCD will then verify the child's attempt to spell the word, by either highlighting the word in green and moving to the next word or highlighting the mistake and prompting the student to try again. This project seeks to apply computer engineering principles, including the use of an embedded system such as the MSP432, power supplies, and a limited mechanical interface, to demonstrate the effectiveness of interactive learning and instantaneous feedback in youth education.

Background

In recent years, there has been a growing influence of technology and gamification on education. Educational technology has supplemented classroom teaching by helping children learn easier, faster, and cheaper. Furthermore, research has demonstrated that the use of educational games significantly improved students' understanding and retention of classroom topics. A recent study found that learning English spelling through a game is more effective than learning English spelling from a traditional classroom setting, as students were able to remember the English spelling easier and found the gamified version very useful [1]. Other benefits to gamified learning include reducing student anxiety to learning new languages, providing immediate feedback, modifying a student's learning level, and creating a stress-free environment [2].

The purpose of this project is to design and implement a spelling game in order to facilitate spelling practice for children aged 5-7. To play this game, the device will show an object on the screen, as well as blank lines corresponding to how many letters are in the word. The user will have to find the correct letter blocks to spell the word and place the letter blocks onto the panel. When the user presses the "Check" button, the program will verify the spelling of the word and indicate whether the word is spelled correctly or not.

To our knowledge, this project is novel because it integrates physical letter blocks with gamification. Previous spelling games have existed fully in software as mobile or web applications, like the app "EDUBUZZ" kids spelling game app [1]. By incorporating physical letter blocks, this project also aids the development of fine motor skills and multisensory learning in children. Multisensory learning is a way for kids to engage multiple senses at once, thus improving the memory of the spelling. This method of learning is helpful for kids who learn differently. Children who struggle with visual processing would also struggle with a mobile app that teaches spelling visually. However, there have been some studies that compare multisensory approaches and conventional approaches for spelling that found there is not a significant difference in spelling performance, but indicated more research had to be done to solidify this claim [3]. We aim to build SpellCheck to further such research by proposing another method to practice spelling. Our project will utilize hands-on learning and gamification to engage kids to practice spelling in a less conventional way.

In addition to performing an extensive literature review, our group also consulted with two professors from the UVA School of Education and Human Development who specialize in Elementary Education: Professor Lysandra Cook and Professor Tisha Hayes. With decades of experience working with our target age range, both professors noted that many current teaching tools are cost effective. However, all of these tools require some type of instructor intervention, which can be time consuming if there is a high student-to-teacher ratio. The professors emphasized that a teaching device that students can operate independently to reinforce previously learned topics, such as ours, would be especially valuable. Additionally, the ability for the teachers to input their own curriculum of words would greatly support their teaching.

We will be using our knowledge from our previous coursework to create SpellCheck. All team members have taken the ECE Fundamentals courses which will help in creating the power supply. Shymbolat, who is taking the primary task of designing the power supply, has also taken Electromagnetic Energy Conversion (ECE 3250). Justin, Catlinh, Noah, and Rachel have taken Advanced Software Development (CS 3240) which will help in developing the gamification and UI design. All team members have taken Introduction to Programming (CS1110) and other CS courses that will help with developing the code for identifying the letters and spelling verification. We will also use our knowledge from Introduction to Embedded Systems and Embedded Computing and Robotics (ECE 3430, ECE 3501/2) to work on the embedded systems and develop with the MSP432. Computer Networks (ECE 4457) is also a relevant class for uploading images to the microcontroller. For CAD design of the letters, Rachel and Justin will use their learnings from Introduction to Engineering (ENGR 1624) where they learned 3D printing techniques and CAD design.

Constraints

Design Constraints

Since the Banana Seals team is composed of both electrical and computer engineers, the project must include a team-designed custom Printed Circuit Board (PCB) and include either a microcontroller or National Instruments myRIO [4]. This constraint is a guideline imposed by the capstone course ECE 4440/4991.

CPU Limitations

The team selected the Texas Instruments MSP-EXP432P401R [5] for the CPU based on the large number of GPIO pins and multiple peripheral interfaces. The MSP432 allows for a maximum clock speed of up to 48MHZ, which was more than what was needed for the system, as the maximum clock speed utilized was 12MHZ.

Software Availability

UVA provides an active license for National Instruments Multisim [6] and National Instruments Ultiboard [7], which the team used for schematic and PCB design. In addition, Code Composer Studio [8] was utilized for writing the embedded software code due to its compatibility with the chosen microcontroller. Visual Studio Code [9] was used to program the UI interface, as it is a free IDE.

Manufacturing Limitations

The PCB manufacturer, Advanced Circuits, imposed manufacturing constraints for the printed circuit board. The 2-layer board was required to have a 62 mil thickness, along with specific requirements [10] to meet a student special criteria, with the most significant factors being:

- Maximum board size: 60 square inches
- Minimum 5 mil line/space
- Minimum 10 mil hole size
- Maximum 50 drilled holes per square inch

In addition to these constraints, the size of the enclosure that houses the system restricted the width and length of the PCB. The board needed to fit within the length and width of the enclosure's front panel in order to fit inside of the enclosure.

Economic and Cost Constraints

Because this project is meant for use in classroom environments, one goal was to minimize costs. This project was limited to a budget of $500. Many tools, such as the Virtual Bench, soldering irons, and microcontroller were available without any added cost. However, the majority of the components used to build this project had to be purchased. The greatest cost in this project was the letter identification system and the production of letter pieces. Only 30 letter blocks could be produced and backup components could not be purchased on a large scale.

Environmental Impact

The project's letter panel and letter blocks were made using a 3D printer. The 3D printed materials emit toxic particles which are harmful for humans. Particles released during the printing process can affect indoor air quality and public health [11]. Printed circuit boards also can be concerned as harmful for the environment during manufacturing. Usage of recycled and environmentally friendly materials for the boards, letter blocks, and letter panel is recommended for future productions of SpellCheck. The PCBs used in SpellCheck should be recycled when the device is no longer being used.

Sustainability

The system presents sustainable design, since the team rejected usage of the ion batteries for the power supply [12]. Instead, the team chose to power the system with a wall transformer which powers the system and can be for long term use. Since the D printed parts are made of ABS plastic, they can be recycled easily and ABS is recycled plastic itself [13].

Health and Safety

One safety concern for the system is the design of the letter blocks. Since our primary users are elementary students, we had to consider the size and shape of the letter blocks to ensure that there are no choking hazards or potential sharp objects. The users should be able to engage with the system without constant adult supervision, as a teacher should not be expected to interfere while students are using the learning aid, so the system should be child-safe.

Additionally, since the system does not use reusable batteries for power, the device must be plugged into a wall outlet. This system can pose a risk of electrocution if handled improperly.

External Standards

1. *IPC Standards for PCB Design* - IPC standards outline the general requirements for the design of printed boards. IPC-2221A standardizes track and part spacings [14]. IPC-A-600J sets standards for acceptance criteria for the printed boards, including material, holes, plating, and more [15].
2. *SMD Component Packages* - Surface Mount Device (SMD) components conform to industry standards outlined by Surface Mount Technology (SMT) packages. JEDEC [16] is the leading standardization body for size specifications for SMT packages.
3. *STL (Standard Tessellation Language)* - The STL standard is a file format that stores only the surface geometry of 3D models [17]. The standard was used to communicate between the 3D printer hardware and the computer.
4. *UART (Universal Asynchronous Receiver-Transmitter* - UART is a circuitry block for implementing serial communication [18]. UART was to upload words and images from the web application to the MSP432.
5. *SPI (Serial Peripheral Interface) Communication Protocol* - SPI provides synchronous communication between a master device and peripheral device [19]. SPI was used to communicate between the microcontroller and the LCD display.
6. *Embedded C Coding Standard* - The Embedded C Coding Standard authored by Michael Barr was used to accelerate the software development process and avoid potential bugs [20]. Some standards set by Barr include comment rules, white space rules, and statement rules.
7. *U.S. Consumer Product Safety Standard* - Because our product is designed for children of ages 5-7, we must label our device to contain choking hazards not intended for children under the age of 3, as indicated by 16 C.F.R. Part 1501 [21] and 1500.50-53 [22] of the small parts regulation must meet standards from the U.S. Consumer Product Safety Commission. Our project must also meet the electrical standards as specified in 16 CFR § 1505.5 [23] of the U.S. Consumer Product Safety Commission. This includes:
    1. Switches must be rated at no less than the load they are intended for.
    2. The internal wiring must be fully insulated and all electrical components must be strong enough to withstand voltages and currents specified for this project.
    3. Wires should be free of any sharp edges or corners, and wires should also be fully secure in their connections to provide reliable electrical contact.
    4. Soldered connections must be made secure before soldering.
    5. Current carrying components must be made of electrically conductive materials.

Tools Employed

Many tools were used to design, develop, assemble, and test our project. The tools for each category of our system are explained below.

Hardware

For board design and routing, National Instruments' simulation and design tools, Multisim and Ultiboard were utilized. Multisim was used to create board schematics and footprints for some components. Ultiboard was used for routing and designing the circuit board. Additionally, the FreeDFM service from Advanced Circuits [24] was used to check the PCB for any errors and ensure that the board was ready to be manufactured. 3W Electronics assembled the components onto the PCB [25].

Autodesk Fusion 360 [26] was used to design the components that were 3D printed. The MAE Rapid Prototyping and Machine Labs [27] was used to 3D print the STL files produced by Autodesk Fusion 360. The National Instruments Virtual Bench [28] was used for conducting our hardware test plan.

Firmware

The firmware was written in C using Texas Instruments' integrated development environment, Code Composer Studio (CCS). The testing of the project and firmware utilized existing libraries, including the driver library of MSP432 [29], and GitHub user RudolphRiedel's FT800-FT813 library adaptation [30] for the EVE TFT display. We determined this library adaptation was acceptable due to its MIT license.

Software

GitHub [31] and Git [32] were used for managing version control of the software and firmware. Github hosted our codebase and allowed for easy collaboration between software developers. The website application was written in JavaScript [33] and Cascading Style Sheets [34] using the React Native development framework [35], and deployed using Vercel App [36]. The application was written in the integrated development environment Visual Studio Code.

Ethical, Social, and Economic Concerns

The purpose of this project is to help students practice spelling, by verifying and correcting students' spelling of simple objects. However, with the advancement of educational technology comes the risk of displacing jobs in education. This project aims to create an inexpensive option for students to practice spelling, which will be cheaper than hiring an instructor. While this device can aid student learning, it is designed to be used in conjunction with classroom instruction as a reinforcement tool, rather than a replacement for traditional teaching methods. SpellCheck does not teach spelling, but rather helps students practice spelling words they have been taught in their classrooms. This concept is supplemented by our website that allows teachers to upload their own word lists from their lesson plans.

To ensure that our device can be accessible to all students, it is important that the cost of SpellCheck is low. If the device is too expensive to reproduce, some school communities may not be able to afford the device, and therefore our project would not be accessible to all students.

Another concern for our project is that the current version of the device is not fully usable by all students. Our device is currently not suited for those who are blind or visually impaired. Our device relies on the user to be able to view the LCD display and different colors. More accessible features such as sound and braille on the letter blocks are considered in the Future Works section later in the report.

Intellectual Property Issues

This project does not have the potential to be patented, because some prior inventions could be found that fundamentally encompass our project design. Three patents that encompass similar material are described below.

One patent presents a "Collective word building and spelling game" [37]. The main claim includes "A collective word building and spelling game comprising: multiple sets of the 26 letters of the English alphabets". While our project includes letter blocks that encompass the 26 letters of the alphabet, our project stretches beyond the scope of this patent to include electronic validation. In light of this claim, our project is still patentable.

One previous patent presents a "block-type board game using a word alphabet puzzle" that was developed for educational purposes [38]. This patent's main independent claim includes "A printed portion .. with one of alphabets, Korean consonant / vowel, numerals and symbols on the upper end of a hexahedron body", "A word block board … having a structure including an attachment plate … made of an iron plate or a magnet", and "constructing a maze through a process of learning the spelling and arithmetic of the word, thereby performing a maze game." Some components of the patent are similar to our project, including the letter blocks and magnetic slots. However, the fundamental difference compared to our project is that this patent does not use electronic verification. Therefore, our project is still patentable in light of these claims.

Another previous patent presents an "English word spelling game" [39]. The main independent claim states that the device "is characterized in that, comprise housing, is arranged on the primary controller of enclosure interior, accumulator, display screen, pilot lamp, loudspeaker, control panel, spelling plate and 52 letter cards". This patent is very similar to our project in that the user must spell out a word using letter cards and displays a verification of the spelling. The differences between this patent and our project is that the patent device says the word to spell using a loudspeaker while our project displays the object on a display, and the patent device verifies the spelling using the color of a pilot lamp, while our project displays verification on the screen. Additionally, the letter cards in the patented device are bonded to the receptacle using a magnet, while the blocks on our project are stuck onto pegs. While there are some differences between the two projects, our project is fundamentally similar to the patented device, and therefore cannot be patented.

Detailed Technical Description of Project

The goal of our project was to build an educational tool that helps children practice spelling. The user must use the letter blocks to spell the image displayed on an LCD display. Each of the

letter blocks are encoded with unique binary codes using different magnet formations. The letter blocks are placed in slots where magnetic hall effect sensors will detect the magnet formations. Our microcontroller will then decode the formation and verify the spelling of the input detected. If the entered word is correct, the microcontroller will send a new image to the LCD to display. The system design was broken down into the following sections:

1. Hardware
    1. Power Supply
    2. Letter Sensing System
    3. Connection to MSP432
    4. Connection to LCD
    5. Board Layout
2. Firmware
    1. Letter Detection
    2. Verifying User Input
    3. LCD
3. Software
    1. User Interface
4. Mechanical
    1. CAD Design
    2. Assembly

Block Diagram

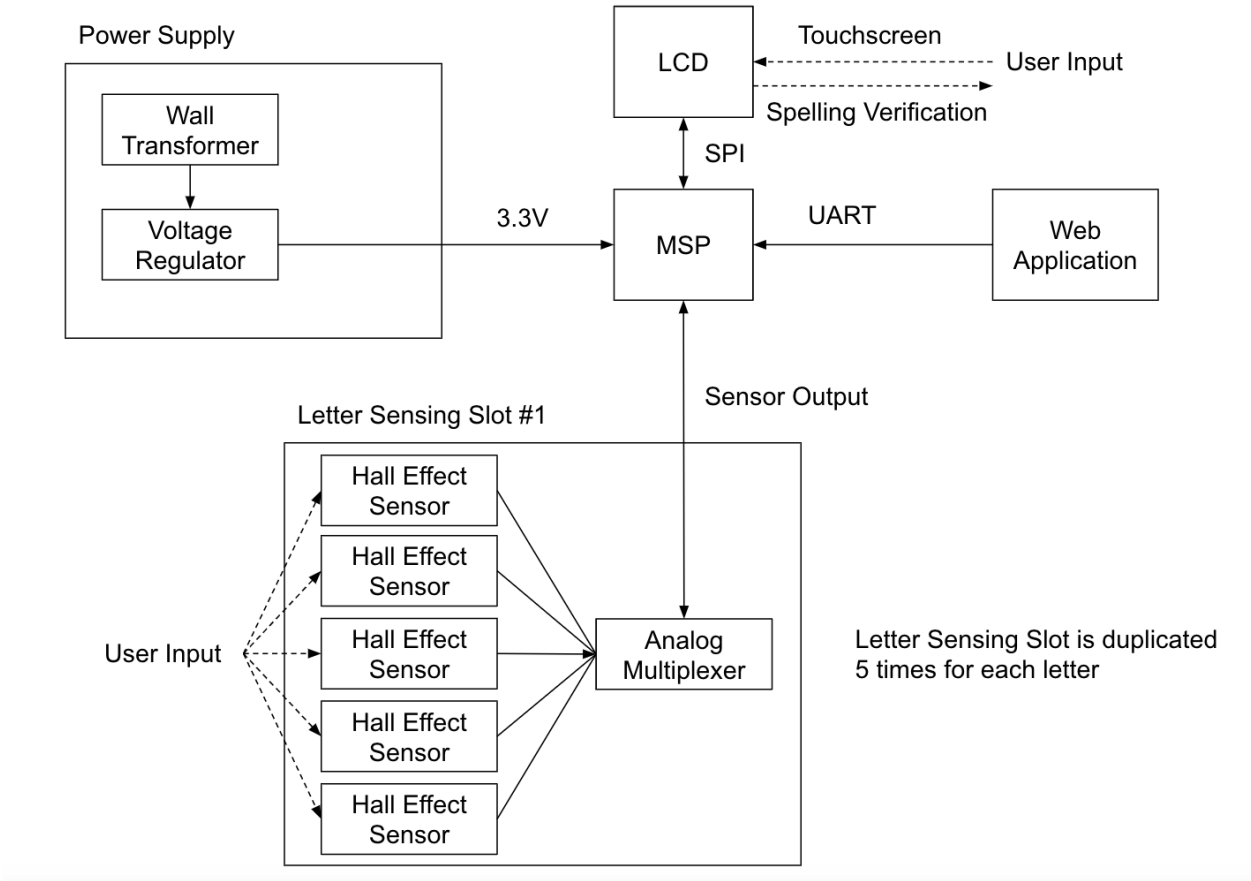

Figure 1: Fully System Block Diagram

Figure 1 displays the full system block diagram of the SpellCheck system. The power supply plugs the device into a wall socket and regulates the voltage to supply the MSP432 with 3.3V. The MSP controls the logic and interfacing with the other components of the system. The MSP first displays an object on the LCD using SPI. The user then puts letter blocks into the slots and the MSP reads and decodes the user's input. The MSP then uses SPI to display a verification of the spelling guess onto the LCD. Additionally, the user may upload their own list of words and images from the web application via UART.

Hardware

The hardware system is a PCB, designed as a booster pack that attaches onto the MSP432. This PCB comprises a power supply, connection to an LCD display, connection to an MSP432 microcontroller, and 5 letter sensing slots. The power supply powers the entire system via connection to a wall transformer. The LCD display interacts with the user by displaying images, reading user touch input, and displaying spelling verification. The MSP432 controls the logic for the system. The letter sensing slots detect which letter blocks were placed into each of

the five slots. The schematic was designed using Multisim and is shown in Figure 2. Each subsystem is described in detail in the following sections.

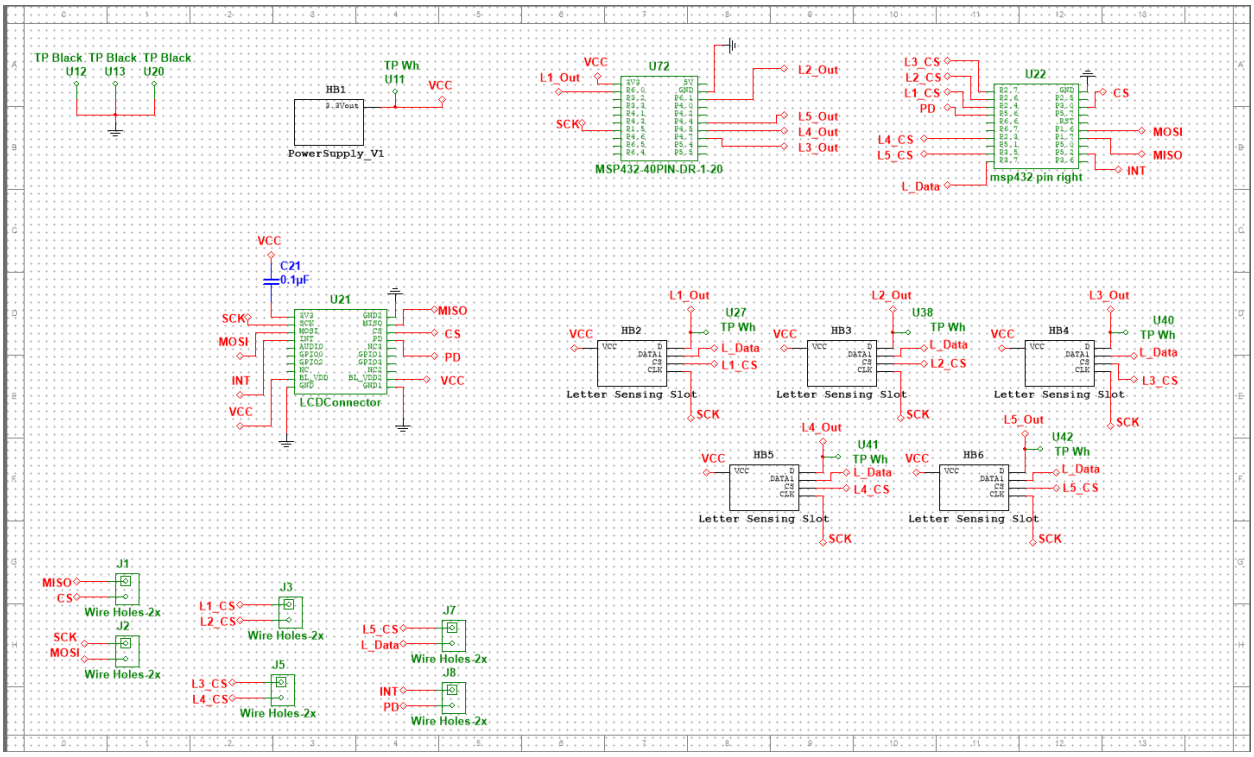

Figure 2: Overall Schematic of SpellCheck System

Power Supply

The SpellCheck system is powered by a wall transformer that connects to a barrel jack connector on the PCB. Figures 3 and 4 display the power supply block and the hierarchical subsystem of the power supply.

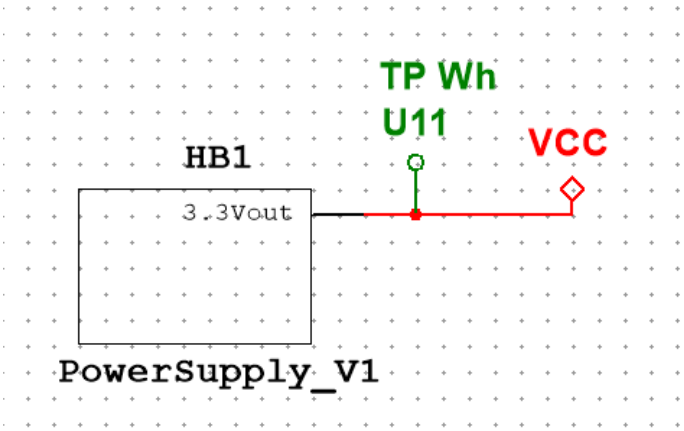

Figure 3: Power Supply Block

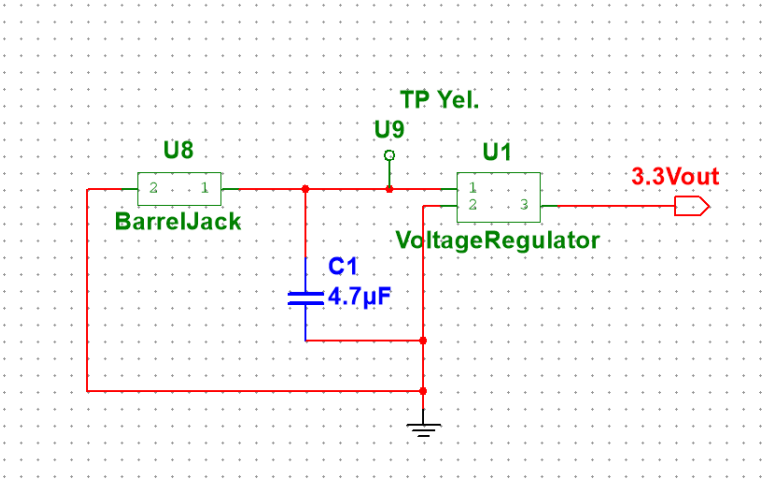

Figure 4: Power Supply Schematic

Component	Current (mA)
LCD	280
Hall Effect Sensor (25)	82.5
MSP	100
LTC MUX (5)	10
Total Consumption	**472.5**

Table 1: Current Consumption of Components

Table 1 illustrates the current analysis of the system required for the voltage regulator R-783.305 where output is 500mA. The maximum current consumption of the whole system devices is 472.5mA. Our device requires 1.6W (3.3V*472.5mA) of power. The regulator delivers 1.8W at 81% efficiency. Therefore, the R-783.305 voltage regulator characteristics are enough for the system.

Letter Sensing System

Letter Slots

In order to determine which letter block was placed into each slot, each letter block is configured with a different combination of magnets. Because there are 26 letters, 5 binary values is sufficient to represent all letters. By placing Hall Effect (magnetic) sensors in each letter slot, reading the combination of magnets, and decoding this combination, we can determine the letter block that was placed in the slot and check this letter against the correct answer. The encoding scheme of magnets is displayed in Appendix A Figure 27 and the method of reading a binary value from a letter block is shown in Figure 5.

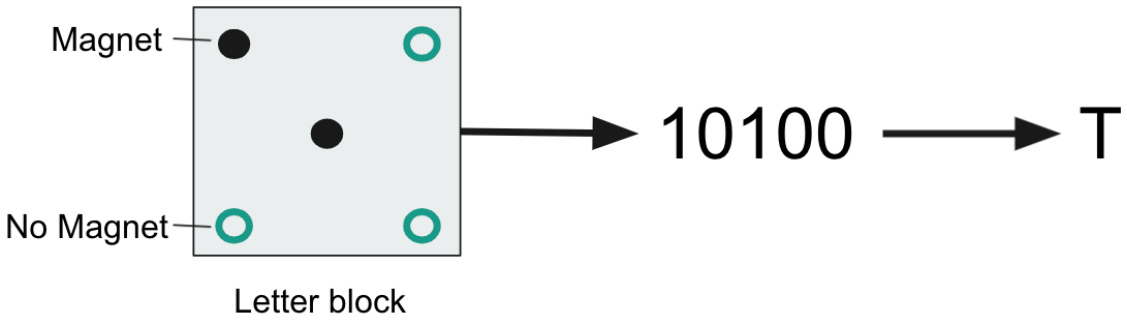

Figure 5: Letter Decoding Example

Hall Effect Sensing

Hall Effect sensors were used to detect different magnet combinations. These sensors have three pins: VCC, Ground, and Vout. Based on the range $(-B_{SAT} < B < +B_{SAT})$ of the strength of the detected magnetic field, the Hall Effect sensor will output a voltage that is linearly proportional to the strength of the field. Beyond the linear range, the voltage output stays at a constant level. The DRV5053 Analog-Bipolar Hall Effect Sensor [40] was selected because it supported a 3.3V input without requiring a voltage regulator, had high temperature stability, had sufficient sensitivity, and produced an output voltage that was detectable by the MSP432 analog I/O pins.

The greatest source of uncertainty revolved around the strength of the magnets. While the magnets had to be strong enough to be detected by the Hall Effect sensors through the plastic slot, the magnets also had to be weak enough to not interfere with the readings of other magnets within the same block. If a magnet was too weak, it would not be detected at all by the sensor. On the other hand, if a magnet is too strong, nearby sensors corresponding to other magnet holes would detect the signal and show that there was a magnet in place, even if there was not. Both of these scenarios would result in inaccurate readings.

In order to mitigate this issue, magnets were specifically chosen such that they were strong enough to put the sensor in saturation range. In other words, any magnetic field stronger than the saturation value would generate a steady voltage reading from the sensor (1.8V for the positive polarity or 0.2V for the reverse polarity) rather than varying proportional to field strength. If there is no field detected, the voltage output will be 1V. According to the datasheet for the Hall Effect Sensor, the magnetic field strength to put the sensor in saturation is 73mT, or 730 Gauss. However, this is assuming that the magnet is placed right over the sensor. Because the magnets will need to be sensed from a distance through a thin layer of plastic. We opted to test magnets of two different strengths: 6619 Gauss and 7179 Gauss. Based on the results of testing, we decided that the 7179 Gauss magnets would be best suited for our application, providing significant strength that can be detected by the sensors, without interfering with neighboring sensors.

Hall Effect Sensor System

Each letter block was placed into a letter slot on the PCB that sensed and decoded the letter block magnet configuration. The schematic for one letter slot is shown in Figure 6. Each slot had four inputs and one output, which are explained in Table 2.

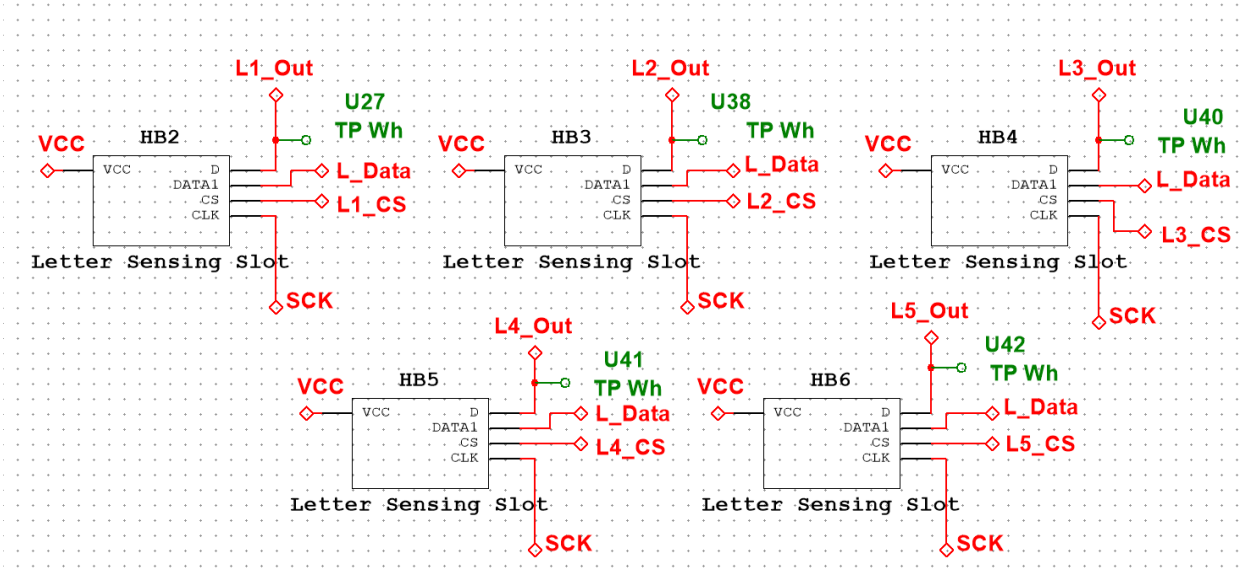

Figure 6: Schematic for One Letter Sensing Slot

Connection	Connection Type	Purpose
VCC	Analog Input	Voltage input
D	Analog Output	Hall Effect sensor voltage output
Data 1	Digital Input	Select line for multiplexer
CS	Digital Input	Chip select to enable multiplexer
CLK	Digital Input	Clock Line

Table 2: Letter Sensing Slot Connections

The letter sensing slot subsystem consisted of a multiplexer and five Hall Effect sensors, as shown in Figure 7. As previously mentioned, each letter block had a different combination of magnets that was read and decoded, with five different potential locations for magnets. Therefore, each letter sensing slot had five Hall Effect sensors that were constantly outputting voltages that are proportional to their detected magnetic fields. However, because the MSP432 has a limited number of analog I/O pins, the voltage outputs from the Hall Effect sensors were connected to different data input lines to an 8:1 analog multiplexer [41]. Based on what value was passed into the multiplexer Data 1 select line, the multiplexer passes the voltage value of a different data input line to its singular output. Therefore, we used software to loop through each of the multiplexer inputs and read each sensor voltage output. If the voltage reading of a sensor

exceeded the threshold that determines the presence of a magnet, this value was decoded as a 1. Otherwise, the value was recorded as a 0. Thus, for each letter sensing slot, we read a 5-bit binary value that could then be decoded as a letter according to the encoding scheme displayed in Appendix A Figure 27.

This subsystem was repeated four additional times to create five total letter sensing slots. The schematic for all five slots is shown in Figure 8.

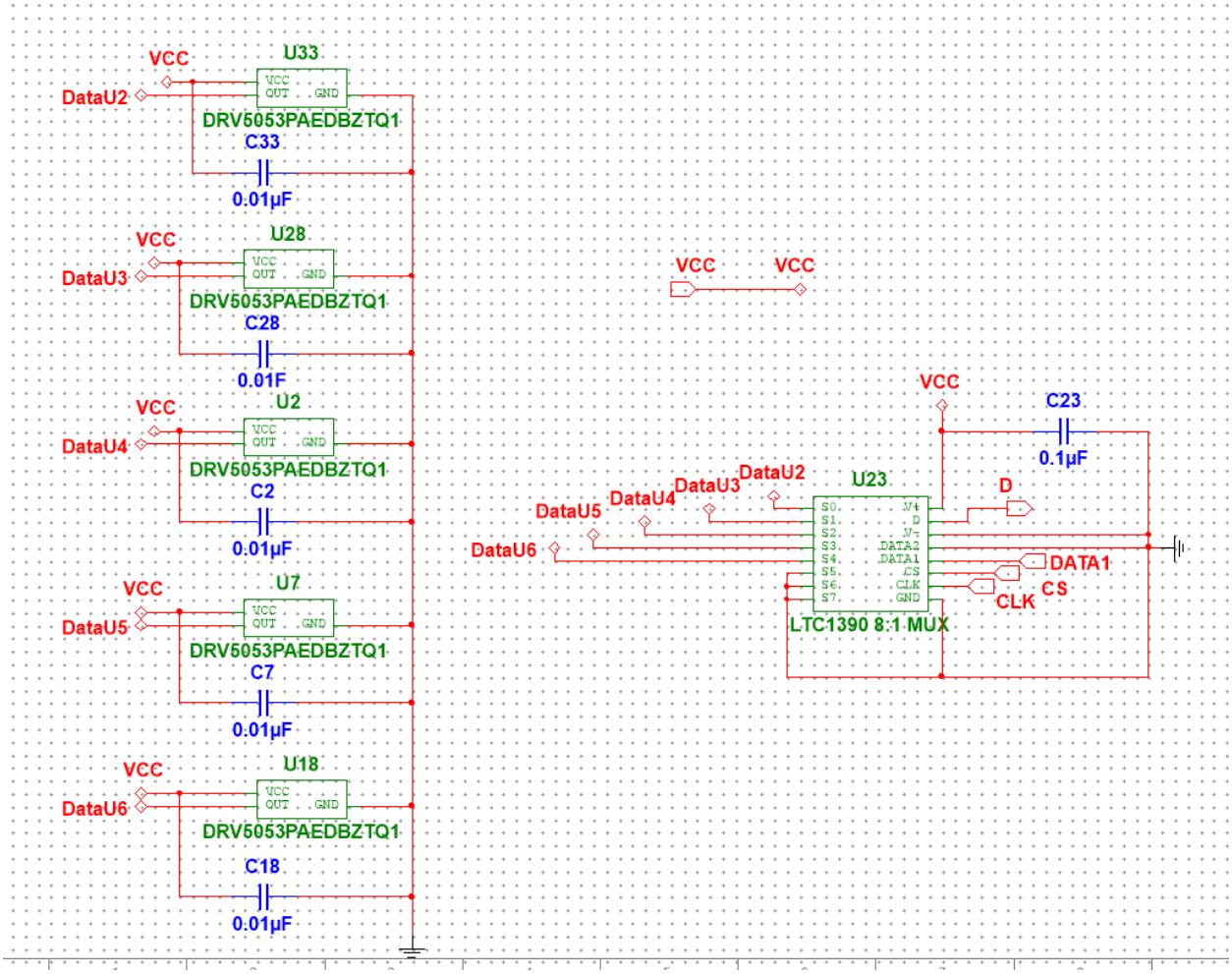

Figure 7: Hierarchical Subsytem Schematic of One Letter Sensing Slot

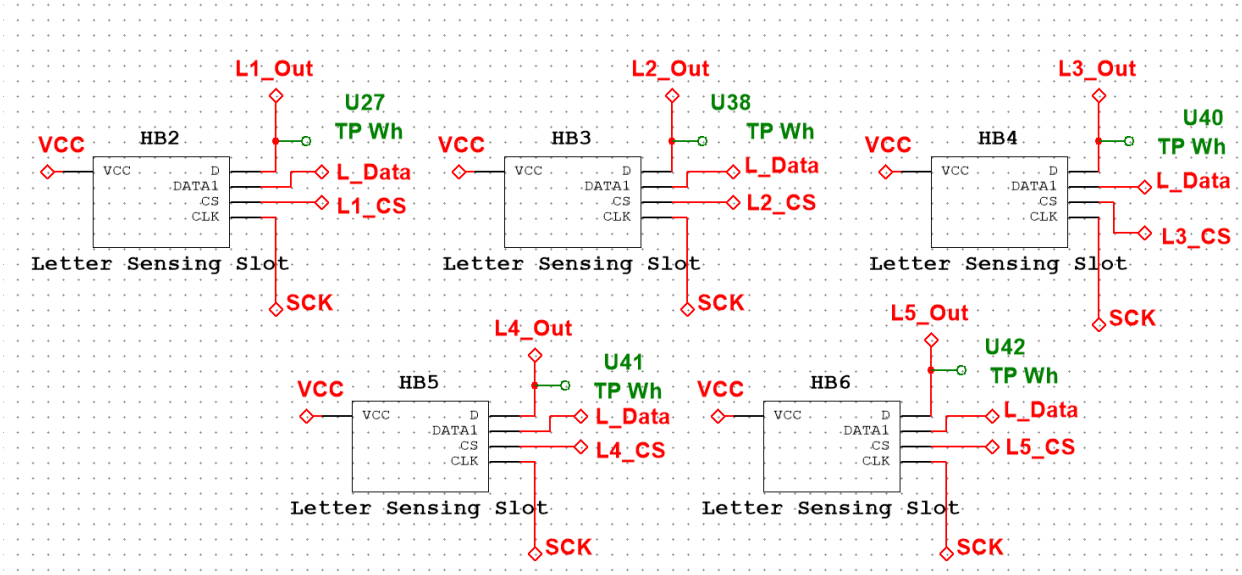

Figure 8: Schematic for All Five Letter Sensing Slots

Connection to MSP432

As previously mentioned, the MSP432 controlled the logic for the entire system. This microcontroller interfaced with the LCD display, as well as the multiplexers and sensors. Figure 9 displays the schematic for the header box connections to the MSP432 header pins. Each of the sensing slot outputs (LX_Out) was connected to an analog I/O pin. The other letter sensing slot lines (SCK, L_Data, LX_CS) were connected to GPIO pins suited for digital I/O. Additionally, because the MSP interfaced with the LCD using SPI, the designated SPI pins on the MSP were connected to the corresponding pins on the LCD connector.

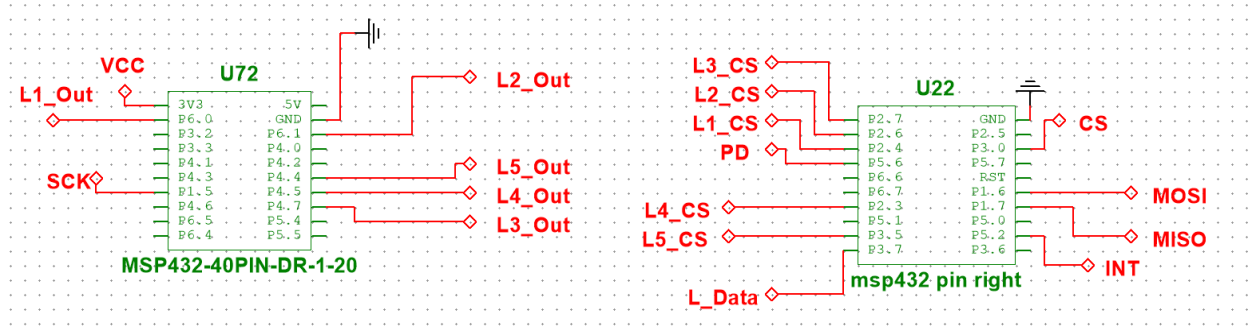

Figure 9: Header Pin Connections to the MSP432

Connection to LCD

As previously mentioned, the LCD communicates with the microcontroller via SPI and the connections are shown in Figure 10. Additionally, the voltage input VCC was connected at 3 points: 3V3, BL_VDD, and BL_VDD2. These connections power the LCD display and the LCD backlight, respectively.

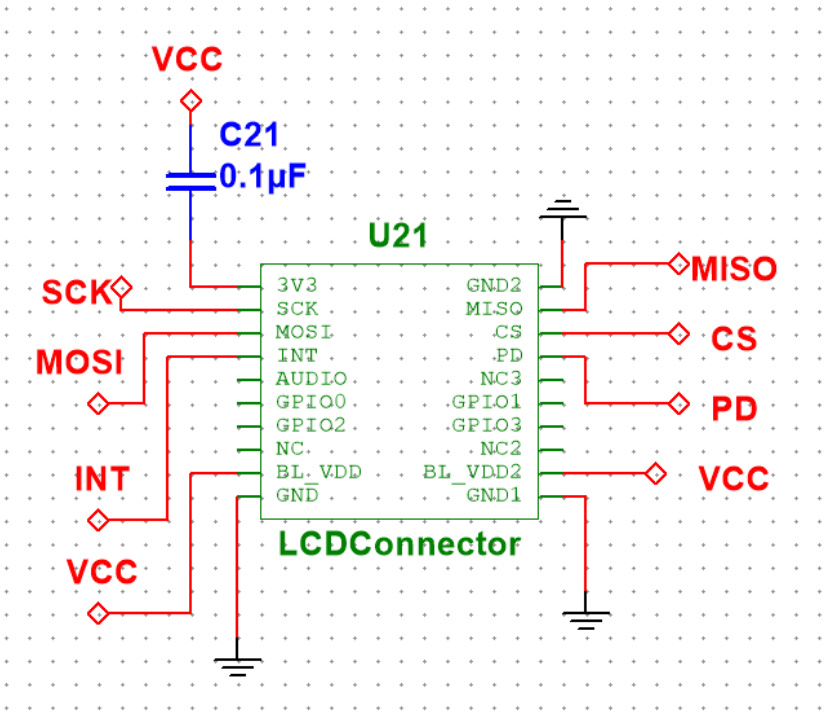

Figure 10: Connections to the LCD TFT Display

Board Layout

The PCB was designed to attach directly onto the MSP432 header pins on one side and sense the letter blocks on the other side. Additionally, the board size was constrained to the size of the enclosure that houses the device. Figure 11 displays the board layout of the PCB. Along the middle row of the board were the Hall Effect sensors, which were placed specifically to line up with the 3D printed letters slots and blocks. It was important that these sensors were perfectly aligned in order to accurately read the magnets through the 3D printed slot panel. Additionally, the board was laid out such that the sensors were the only components mounted to the bottom of the board to minimize the distance between the magnets and sensors. All other components were mounted to the top of the board. Lastly, the footprints for the barrel jack and LCD connectors were strategically placed on the left side of the board to allow cables to feed through the opening in the enclosure.

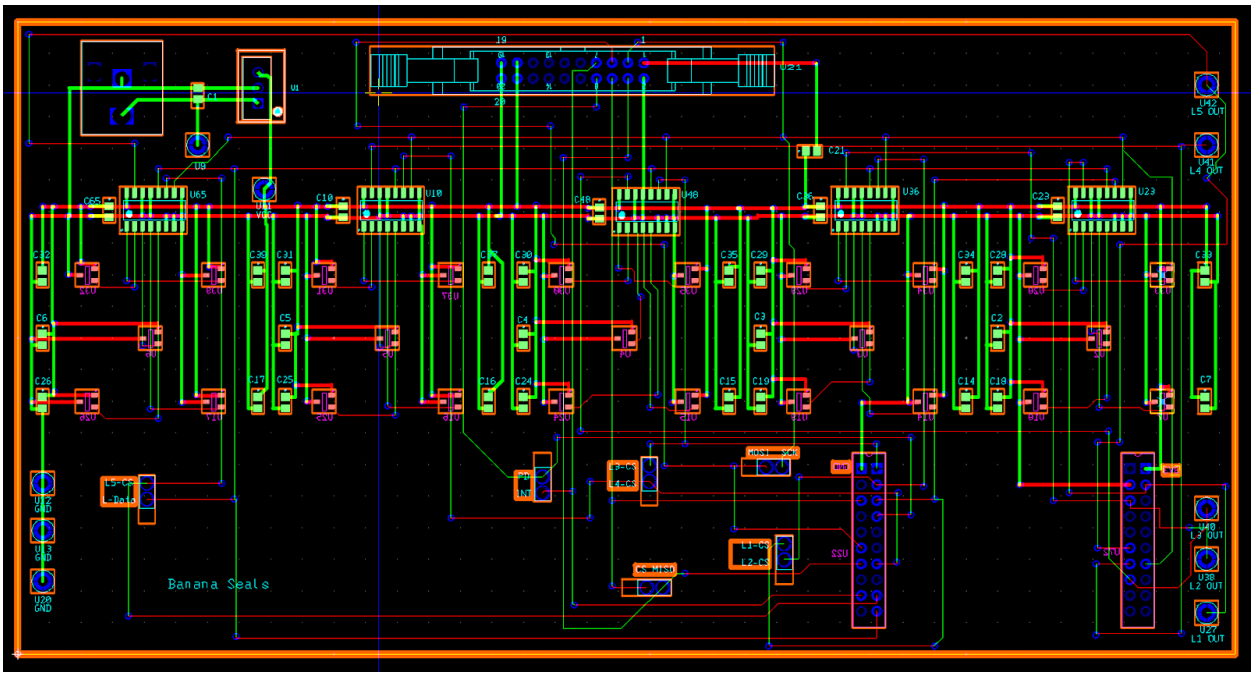

Figure 11: PCB Board Layout

Firmware

Letter Detection

As previously mentioned, each letter was encoded as a different combination of five possible magnet locations. Therefore, in order to determine what letter block had been placed in each slot, each Hall Effect sensor had to be read, and the combination of readings had to be decoded. The first step of this process was to determine whether or not a magnet was detected above a given sensor. The Hall Effect sensor generated a voltage output proportional to the detected magnetic field that was sent to an analog input pin on the microcontroller. This analog value was passed through analog-to-digital conversion (ADC) to convert the voltage to a digital value. This digital value for the Hall Effect sensor output was checked against a threshold value that was determined via testing, to determine whether or not a magnet was detected or not. Because each magnet had both a positive and negative polarity, a magnet was marked as detected if the voltage output was below the negative polarity voltage threshold or above the positive polarity threshold. Any voltages measured that fell in between the two threshold values were marked as having no magnet.

Each of the Hall Effect sensors corresponding to one letter sensing slot were connected to different data lines of an 8:1 analog multiplexer. The purpose of the analog multiplexer was to gain the ability to read five different sensors only using one pin on the microcontroller. By iterating through each of the multiplexer select lines, each data line could be read, allowing us to record the readings of each Hall Effect sensor in a slot. This multiplexer and sensor configuration was replicated five times to represent five total letter slots.

Verifying user input

Figure 12 displays a software flow diagram for how the system verifies the user's input from the letter blocks. First, the system polls the Check button on the LCD to monitor when it has been pressed. Next, we iterate through each multiplexer select line and iterate through every letter slot to read each Hall Sensor voltage through the ADC. If the ADC value is greater than THRESHOLD_HIGH or less than THRESHOLD_LOW, the binary value for that slot and line is recorded as a 1, indicating that the sensor detected a magnet. Otherwise, we store the value 0 into the respective slot and line. This process is repeated for all select lines and letter slots. Once the 5-bit binary value is stored for every single letter slot, each 5-bit value is decoded as a letter. If the binary value is 00000, the letter is decoded as an empty slot. The letters for all five slots are concatenated to form a word. The word is then compared against the correct answer. If the guess is correct, we highlight the user's guess on the LCD in green and display the next image for the user to spell. If the guess is incorrect, we highlight the incorrect letters in red and prompt the user to guess again. This process repeats every time the user presses the Check button on the LCD.

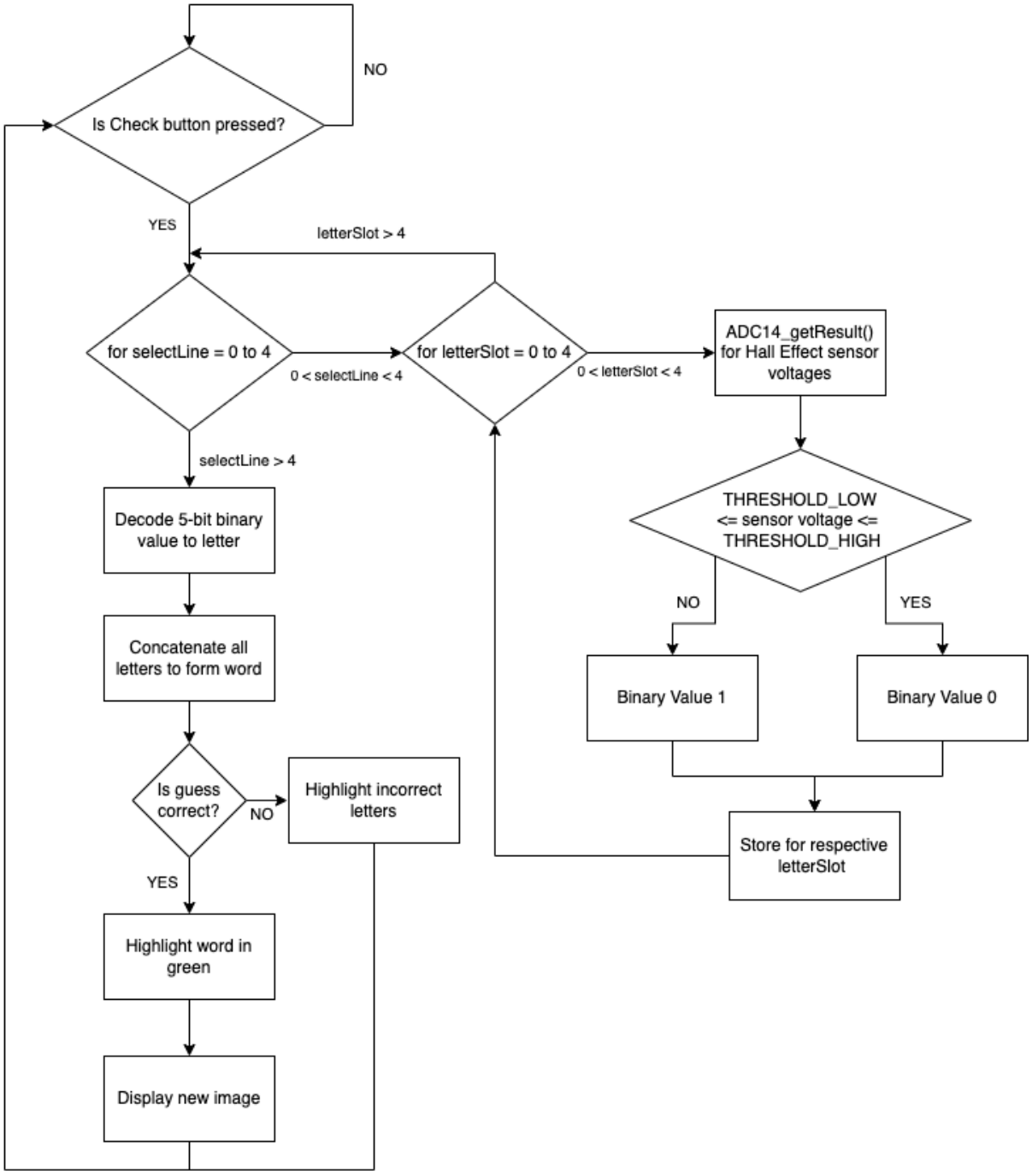

Figure 12: Software Flow Diagram for Letter Verification

LCD

The TFT LCD display interfaced with the MSP432 microcontroller using the serial-peripheral interface (SPI). SPI communicates using four data lines: CLK, MOSI, MISO, and CS. The CLK serial clock line synchronizes communication, MOSI sends data from the MSP to the LCD, MISO sends data from the LCD to the MSP, and CS chip select determines which direction the data is being sent. The microcontroller uses SPI to write commands to the EVE

display engine on the LCD. Images are downloaded from the web application and stored in the MSP's flash memory. Then, the MSP writes the images to the LCD and these images are loaded into the LCD's RAM memory. Then, the LCD loads the image bitmap from RAM to display the image when needed.

Software

User Interface - Front End

The SpellCheck website is deployed on Vercel App and can be found at https://spellcheck-client.vercel.app/. The website uses an open source template from GitHub user briancodex for the user interface design [42]. The website's main purpose is to provide an interface for teachers to easily upload word sets from their lesson plans to be used on the SpellCheck device. Figure 13 shows how a user can upload images to the device.

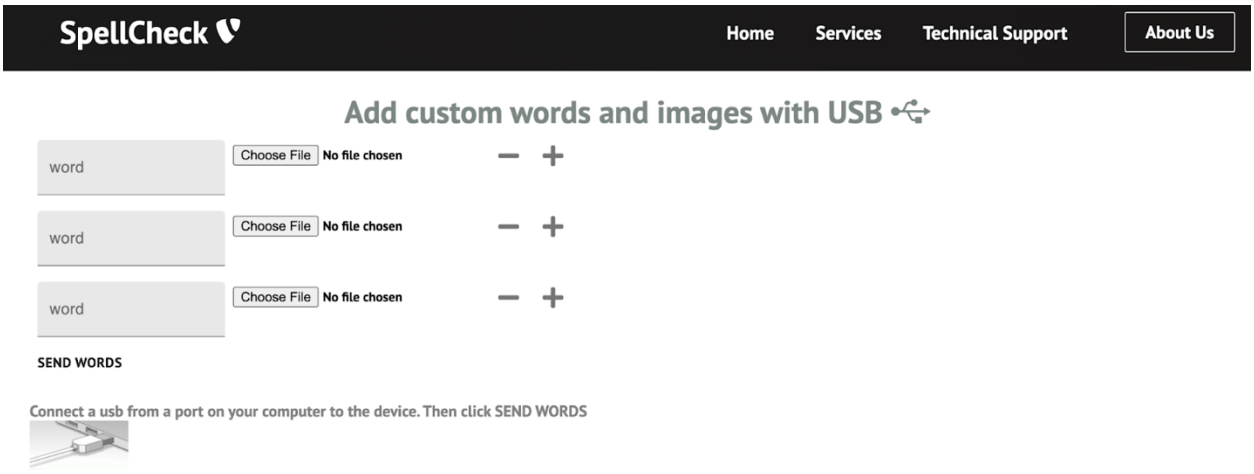

Figure 13: SpellCheck Website Custom Words Form

From a user perspective, the user will navigate from the home page of the website to the services tab and select either "Custom Words & Images" or "Default Words & Images" to upload words onto the device. To enter their own images, the word/image pair must follow the following constraints:

- Image files must be .png or .jpg/.jpeg
- Word can be no more than five lowercase letters
- Word and image fields must be filled

If any of the constraints are violated, an alert message will be displayed to the user. Once the user submits the words (their own custom words or the default words), the user will be prompted to select a COM port for the device (the device must be plugged in for the ports to appear). A loading icon will appear on the screen until the words are successfully uploaded and a success alert will appear to the user.

The website also provides a technical support page if users need to resolve common problems and are unfamiliar with the device. The following section will explain in further detail how the system receives the images and their corresponding information.

Uploading Images to the MSP432

Once the user uploads their image and word onto the web application, the application must load the information onto our device. Figure 14 displays a software flow diagram of the image uploading process. First, the web application checks that the text is valid (5 letters or less) and that the image is either a .png or .jpeg/.jpg file format. When an image is selected, the react-image-file-resizer module dynamically resizes the image and optimizes them for picture quality. Next, an object is created containing the image and its properties, including file size, height, width, type (jpeg or png), and a unique identifier matching the unique identifier of the image's respective word. If the user would like to upload a new image and word pair, the new input is mapped to a new unique identifier. The user may also remove previously uploaded words.

Once the user presses the "Send Words" button, the program searches for all of the words and image objects with the same unique identifier and stores the information into a new processed array containing an object. The object has the following field: word, file, image size, height, width, and file type. Any items with a unique id that does not appear in both arrays are not added to the processed array. In order to communicate all of this information to the MSP over UART, all fields are concatenated into a string. In this string, each field is followed by a specific delimiting character to indicate what the field represented: '|' for word; '/' for file; '$' for file type; '*' for file size; '#' for image width; '!' for image height. Additionally, '%' is added at the end of each word/image pair to indicate the end of data being sent for a segment , '.' is added once at the end to indicated the end of the data stream, '+' is added as a dummy/buffer character to resolve timing issues encountered by the microcontroller. Finally, this concatenated string is passed into the TalkToMSP(string) function that converts the string to a javascript array which is sent over the COM port that has been selected by the user. This function also listens for an ACK signal from the microcontroller. If the ACK was successfully received, the image was successfully transmitted and the stored array is cleared. If not, the image transmission failed.

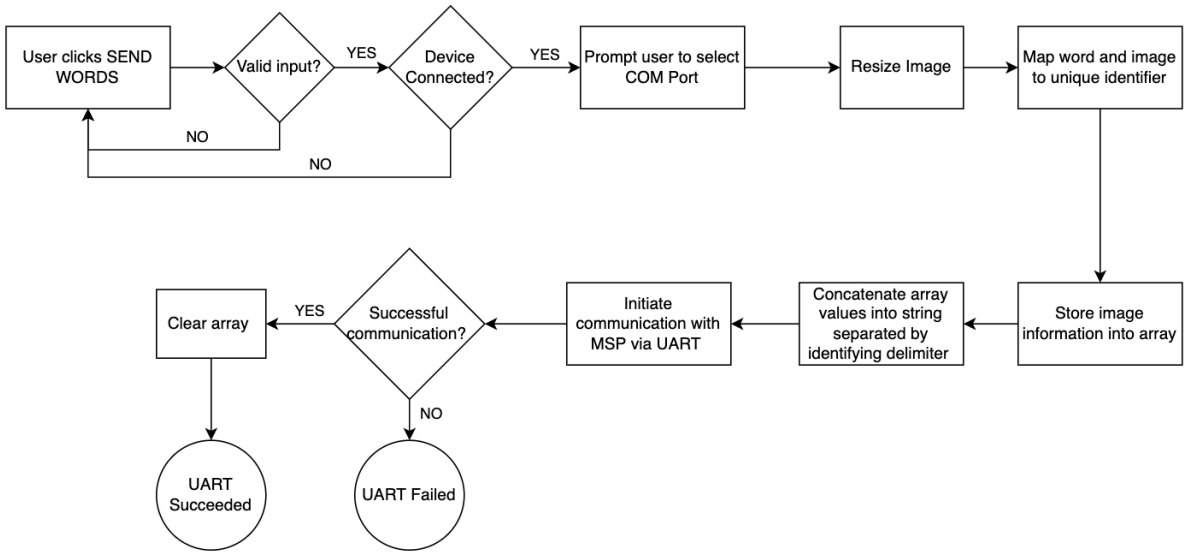

Figure 14: Software Flow Diagram for Uploading Images to MSP432 from Web Application

Mechanical

CAD Design

There were two components of our system that were 3D printed. First, the letter blocks had to be designed to interface with the magnet identification system. Second, the slot panel for the attempted word had to be designed to fit onto the chosen enclosure and ensure letters were placed in a certain orientation.

For the letter blocks, the size of the letter block was chosen based on the size of a standard toy letter block [43]. Holes for the magnets were put in the four corners and middle of one side of the block to maximize the spacing between the magnets to decrease any interference between magnetic fields. Since the orientation of the letter block is critical for correctly identifying the letter, an indentation was placed onto the bottom of the letter block that would make the letter block fit onto the panel in one way. Finally, the bottom of the letter block was shelled to minimize the cost of 3D printing each letter block. It should be noted that the block should be filled in the areas that were shelled to ensure the singular block orientation. Due to cost

constraints, our project's letter blocks are not filled. The final CAD design for the letter block can be seen in Figure 15.

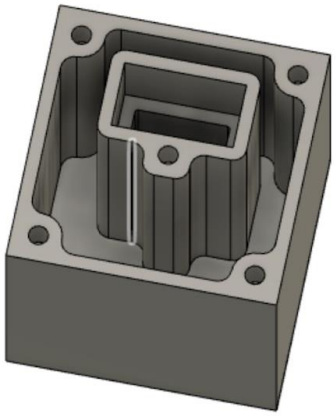

Figure 15: Letter Block CAD Design - Bottom of Block

For the slot panel, the height, length, and width of the panel reflected the measurements of the given panel from the chosen enclosure. Five indentations were placed onto the panel to indicate where the letter blocks should be placed, along with the peg shape that would fit inside the indentation designed on the letter block. Four holes were placed on the corners of the panel so it could be properly mounted onto the enclosure and secured in place. The final CAD design for the panel can be seen in Figure 16.

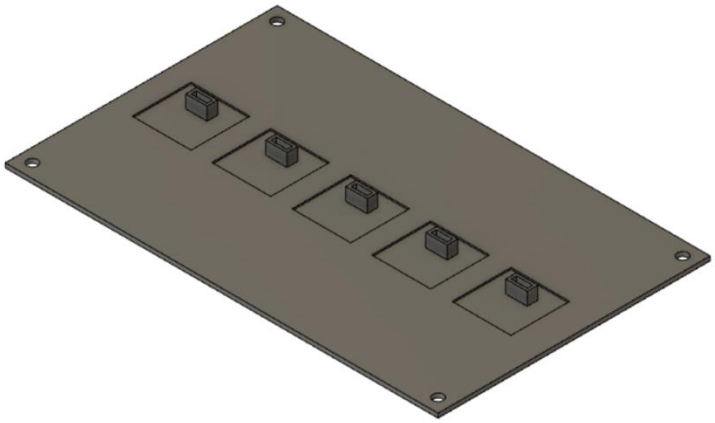

Figure 16: Slot Panel CAD Design

Assembly

Once the letter blocks and slot panel were 3D printed, the magnets had to be placed into each letter block in accordance with the letter identification scheme seen in Appendix A and B. Even though we are able to identify if a magnet was present regardless of the polarity of the magnet, we decided to put the magnets into the blocks with the positive polarity being read by

the sensors to keep the blocks consistent. With this design choice, we increased the number of identification combinations for future blocks.

For the slot panel, the PCB had to be assembled right underneath the panel and the sensors had to be aligned with the block indentations. If the PCB was not aligned with the slot panel accurately, the sensors would not be able to read the magnetic field with the accuracy that we need to decode the letters. Letter identification on the panel with the PCB underneath was tested to find an accurate position for the PCB. The measurements for the PCB were used to then match drill four holes into the panel and PCB, which could then be mounted together using screws.

A phone tripod mount was used to mount the LCD display [44]. The mount was chosen since it could securely hold the LCD and could be attached onto the enclosure using a screw. The mount was within our budget constraints and gave the cleanest look compared to other suggestions.

Project Timeline

The first proposed project timeline can be seen in the Gannt chart in Figure 17. The Gannt chart is categorized in the following subjects: Administrative (blue), PCB (pink), Assembly (red), Software (green), and System Testing (purple). Originally, we expected to simultaneously work on the PCB design, 3D printing designs, and firmware, with most development being completed by the middle of the term. Most of the work was frontloaded, especially the PCB, as we wanted to give our team enough time to order and wait for components. Figure 18 represents an updated Gantt chart that more accurately represents the project's timeline. The team realized that the majority of testing was reliant on component ordering, which was delayed. Software development also took longer than expected and the PCB design was prolonged since the team decided to participate in the first and last PCB orders for the course. LCD related tasks were pushed back due to the LCD Display taking longer than expected to arrive. However, all tasks were still able to be parallelized and towards the end of our timeline the system could be tested as a whole. The team aimed to have a final working system by December 15th.

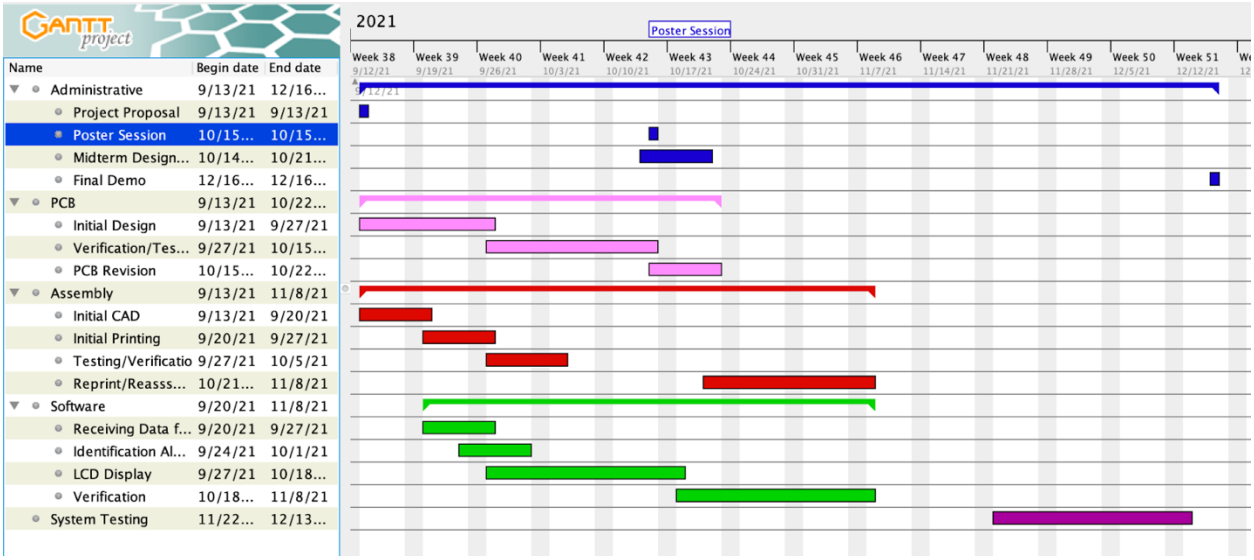

Figure 17: Proposed Gantt Chart

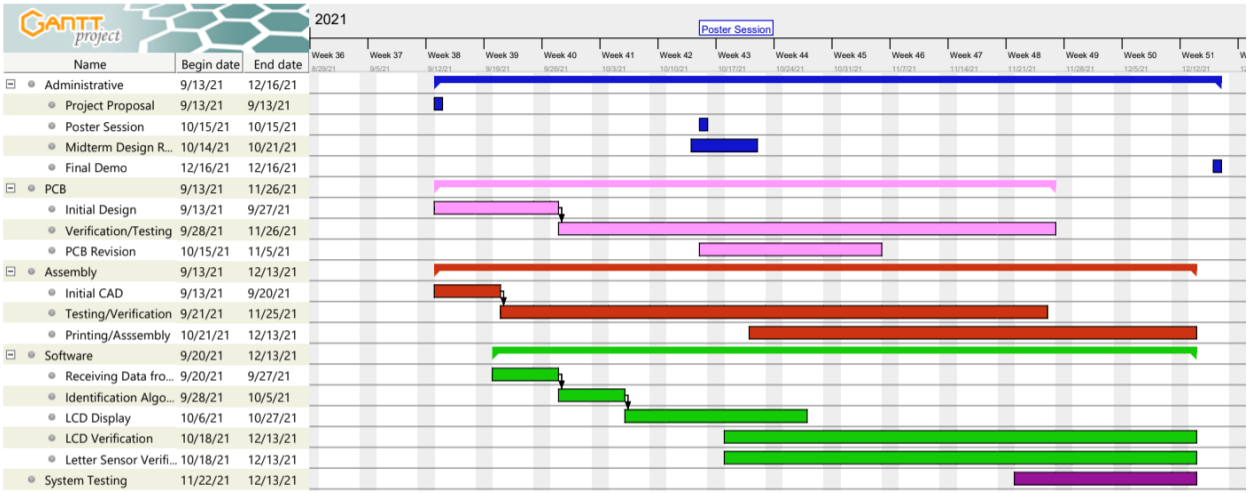

Figure 18: Updated Gantt Chart

The primary tasks of the project have been split among the five team members into primary and secondary roles. Noah's primary focus was hardware communication (mainly the LCD), and assisting the development of the microcontroller software and power supply. Justin's primary focus was developing the microcontroller software application, as well as helping with the letter identification system connections. Rachel's primary focus was the CAD design for the letter blocks and slot panel, and assisting Catlinh with the letter identification system and PCB design. Catlinh focused on designing on the letter identification system, with secondary focuses on letter design and PCB design. Shymbolat focused on designing and developing the power supply, and helped with the hardware communication.

Test Plan

Hardware

Magnets and Sensing

The magnets and sensors were tested in 3 capacities: for interference, for critical distance from the sensor that can produce a reading, and in the device enclosure. Initially, all testing was done with the 6619 Gauss magnet.

Interference Measurements:

As previously mentioned, the greatest concern was whether or not the magnetic field from one magnet could interfere with the sensor that is designated to another magnet. In order to test for interference, different combinations of magnets were tested. For example, one sensor was tested with no magnet in its slot, but with 1, 2, 3, and 4 neighboring magnets. If there was interference with other magnets, the sensor would show a change in its voltage output.

The results of this testing are displayed in Appendix C Table 7. While there was a slight interference in sensor readings in the presence of neighboring magnets, this difference was not statistically significant. Therefore, the presence of each individual magnet is still distinguishable and sufficient to create different detectable magnet combinations.

Critical Distance:

To find the critical distance between the magnet and the sensor to produce a reading, the magnet was tested at different distances from the sensor as the sensor voltage output was recorded. These readings were graphed against the baseline sensor reading of 1.0282V that was measured with no magnet present. The results are displayed in Figure 19.

Note: This graph displays the magnet from the reverse polarity. The results are similar, except the range is from 1V – 1.8V in the positive polarity.

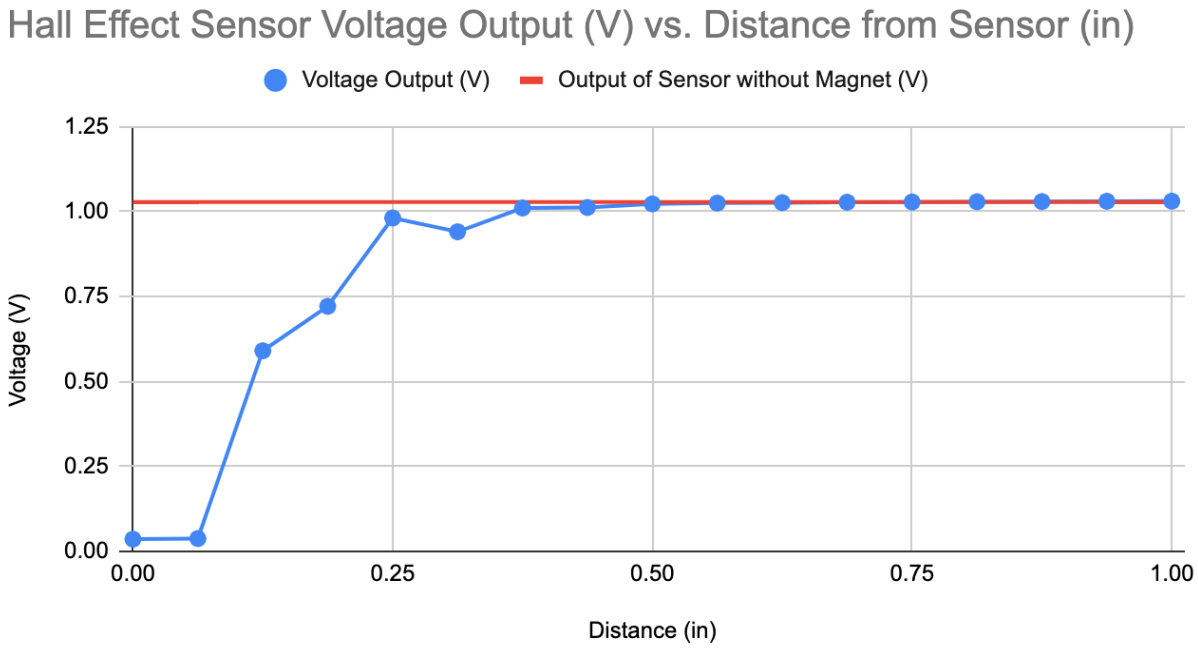

Figure 19: Hall Effect Sensor Voltage Output vs. Distance from Sensor

As shown in the graph, the critical distance between which the sensor can still detect the magnet is 0.19 in. Therefore, as long as the magnet is placed between 0.00-0.19 in, it will be detectable.

Enclosure Measurements:

Both strengths of magnets were inserted into blocks and measured through the slot from the sensors mounted onto the PCB. The voltage output results for each magnet are displayed in Table 3. As expected, both magnets place the sensor in saturation and can be detected by the sensor.

Baseline Voltage Output: 1.0282V

	6619 Gauss Magnet	**7179 Gauss Magnet**
Negative Polarity	0.4814	0.0426
Positive Polarity	1.9995	2.0303

Table 3: Voltage Output from Hall Effect Sensors for Different Magnet Strengths

Preliminary PCB Testing

Before creating a full PCB for our entire system, we manufactured a tester PCB with only the MSP connections, LCD connector, and power supply so that we could start working with the

LCD as soon as possible. Figure 20 shows the schematic for the tester PCB and Figure 21 shows the board layout of the tester PCB.

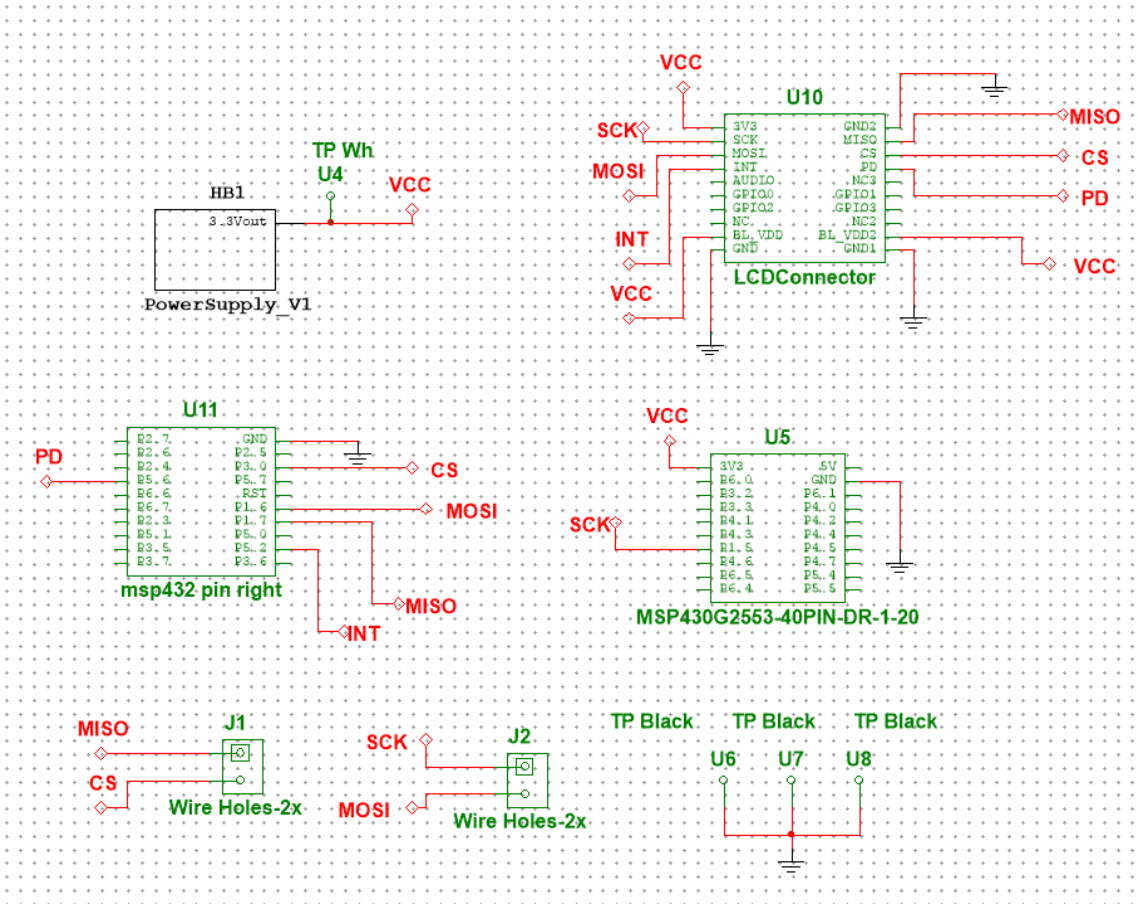

Figure 20: Schematic Drawing of Tester PCB

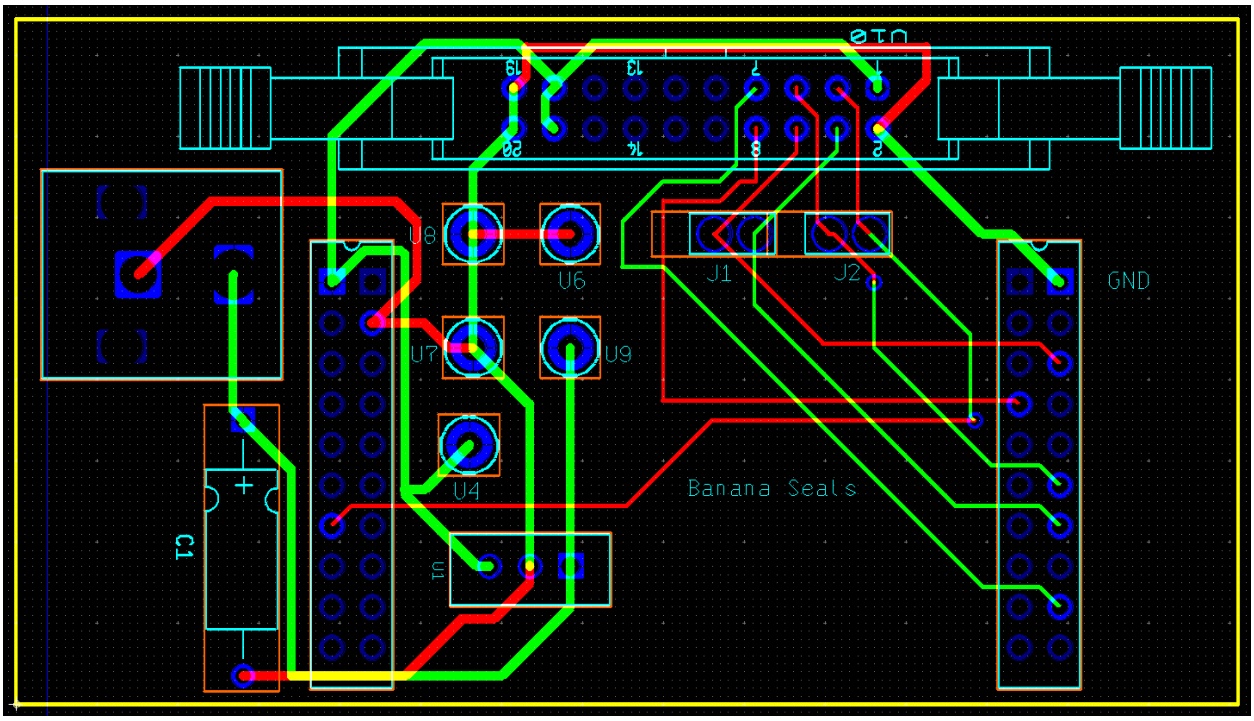

Figure 21: Board Layout for Tester PCB

The power supply had to be verified that it could regulate the voltage from a wall transformer and step the value down to 3.3V, which is the required voltage to power the PCB. In order to do this, test point U9 was connected to the output of the voltage regulator. After the PCB was plugged in, the voltage at this point was measured and found to be 3.3393V, which is similar to the expected voltage of 3.3V. The measurement from Virtual Bench can be seen in Figure 22. Therefore, the power supply operated as expected.

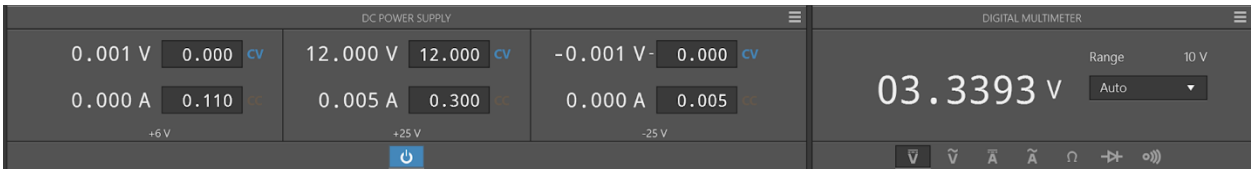

Figure 22: Measured Voltage at U9 for Power Supply Verification

The LCD system was tested so that it could accurately load and display images. After connecting the tester PCB to power and the MSP, we tested that the SPI communication between the MSP and LCD was working as expected. We debugged the system until the LCD could display images and accurately process touch.

Full PCB Testing

The PCB with the full schematic was tested to ensure that all electrical connections were sound and functioning as expected. Because the power supply and LCD connector had already

been tested in the tester PCB, which had a nearly identical circuit, much of this process focused on the sensor functionality and letter identification.

In order to test the sensors, the PCB was plugged in and a voltmeter probe was placed on each of the sensor output lines. A block with an attached magnet was placed on each sensor. Each sensor was verified that it could produce a sufficient voltage output in the presence of a magnetic field.

Next, we had to verify that the LCD could be properly powered by the PCB. If the LCD only had power to its backlight, it would display a bright white screen. If the LCD was properly receiving power to its 3V3 pin and its backlight pins, the screen should turn off. However, when we first plugged the LCD into the PCB, only the backlight turned on, indicating that there was a problem with powering the 3V3 pin. After further inspection, we found that we had improperly connected the bypass capacitor for the LCD in series, rather than in parallel. The incorrect connection can be seen in Figure 23. This was the only change that we had made to the LCD circuit between the tester PCB and the final PCB. To fix this, the capacitor was shorted as seen in Figure 24. This solution solved the LCD powering problem.

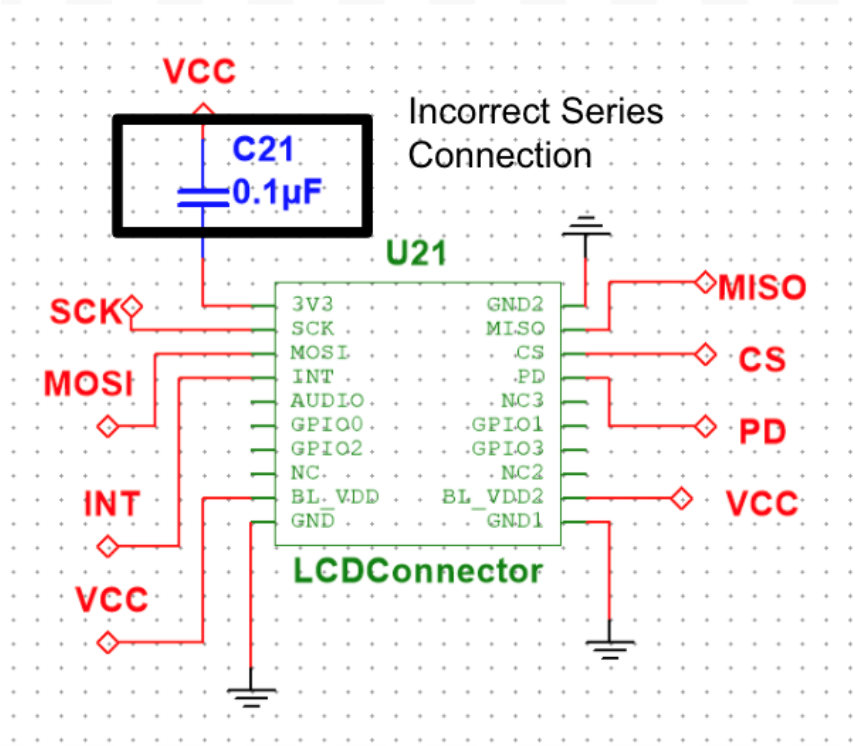

Figure 23: Incorrect Circuit for LCD Connector

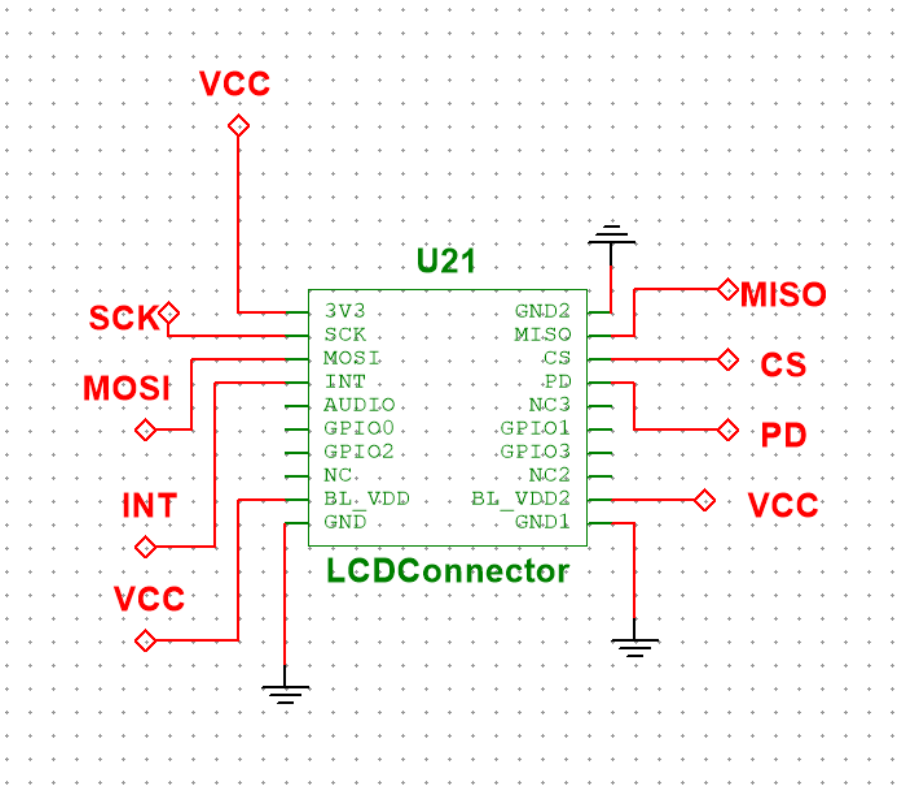

Figure 24: Resolved Circuit for LCD Connector

Software

Figure 25 displays the test plan for the process of uploading images from the web application onto our device. First, we checked that the web application can differentiate between valid and invalid user input. Next, we tested that the web application can detect that the MSP is connected via USB. Next, we tested that UART communication is working between the web application and the MSP. Lastly, we tested that the image and text that were uploaded by the user on the web interface was stored onto the MSP and could be loaded properly on the LCD display. Once all of these points were verified, we had a functioning image uploading system. Furthermore, we tested the web application for seamless user interaction and that the site would not break or crash.

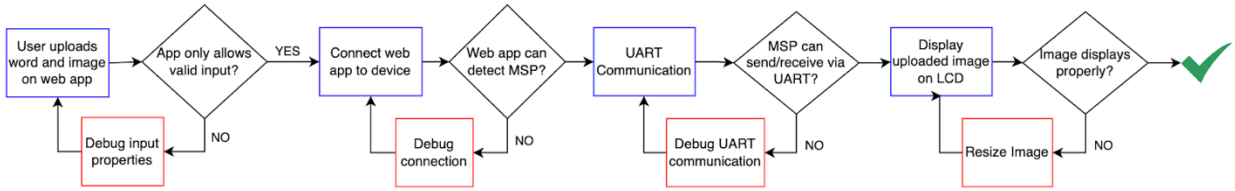

Figure 25: Test Plan for Uploading Images from Web Application

To test the LCD display, the power connections were first verified. The backlight pins, pins 17 and 18, were connected to power. We expected the backlight of the LCD display to turn

on. When the final power port, pin 1, was connected to power, we expected the LCD display to turn off. We verified these actions occurred. Once the power was verified, we checked the SPI connections by connecting the LCD and MSP according to the port mapping we specified in our PCB layout. After sending commands to turn on the LCD and configure its clock, we read the chip identification register. By confirming that the register read 0x7C, which is the value given in the LCD's datasheet, we were able to confirm that the LCD was able to transmit and receive data to the MSP using SPI.

Full System Testing

Figure 26 displays the test plan for the spelling verification aspect of our project, using our full PCB. As shown in Figure 26, the testing was broken up into 3 main sections: LCD display, letter identification, and spelling verification. The LCD system was tested so that it could accurately load and display images. Because we previously verified LCD functionality on the tester board, this part of the process did not require significant debugging, as the full PCB had the same circuitry as the tester PCB. Next, we verified that the letter identification system was functioning correctly. Because we had previously verified that the sensors could produce an expected voltage output in the presence of our magnets and blocks and that the neighboring magnets did not pose any interference, this part of the testing process focused on how to decode the voltage readings into letters. We debugged the multiplexing process, encoding scheme, and decoding process in order to fix the letter identification system. Lastly, we tested the spelling verification flow that is detailed in Figure 12. Because we previously verified that the letter identification process was working and could accurately identify all 26 letters, this segment of the test plan involved debugging software logic. Once this functionality was implemented, we had a basic functioning system.

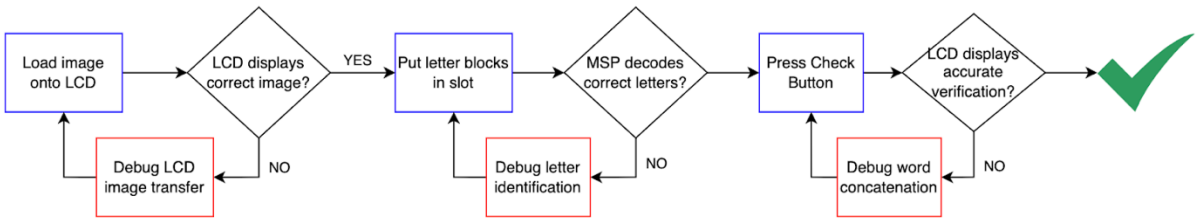

Figure 26: Spelling Verification Test Plan

Final Results

We successfully built a device that helps students practice how to spell. The system contains all of the key components, including an interactive LCD display, letter blocks, child-safe enclosure, and a user-friendly interface for teachers to upload their own word lists. Furthermore, our final project meets all of the key criteria that was specified in our proposal. Tables 4 and 5 show the expectations that we set for SpellCheck in the project proposal. First, letter detection is fully functional and can correctly identify all 26 letter blocks. Second, spelling

verification was implemented and can determine if a user's spelling guess is correct. Next, the LCD display shows the pictures, the user's guess, the spelling verification, and highlights the letters that were spelled incorrectly. However, the LCD display does not implement a user specific game interface. Next, the letter board makes it easy for the user to place letters and has slots for all five letters. Lastly, the Check button on the LCD effectively initiates spelling verification when pressed. However, we did not implement a power button because this can be done by plugging the device into a wall socket. Therefore, the requirements that we satisfy places our project in the A range as defined by Table 5.

	Letter Detection	**Spelling Verification**	**LCD Display Communication**	**Letter Board Placement**	**Button Functionality**
2	Can accurately identify all letters produced	Can determine if target word is spelled correctly or not	LCD display can show not only pictures, but also components of the software game	Letters can be placed and read easily, and fit only in one orientation onto the board. Must have 5 letters onto board.	Accurately initiates spelling verification when pressed. Other button turns on power.
1	Can somewhat identify the letters produced	Can determine if target word is spelled correctly most of the time OR determines correct spelling for wrong target word	LCD display shows only pictures, but not components of the game	Letters can be placed and read easily, but orientation to place in board is not straight forward	One of the functions are correct.
0	Can not accurately identify letters	Cannot determine if target word is spelled correctly	LCD does not show pictures OR does not turn on.	Letters do not fit into the system	Does not work

Table 4: Rubric for SpellCheck Expectations

Points	**Grade**
8-10	A
5-7	B
2-4	C

0-2	D

Table 5: Grading Rubric Key

In addition to the requirements that we set in the beginning of the semester, our team implemented extra functionality that makes the device easier to use and more effective. In our conversations with Professor Cook and Professor Hayes from the UVA School of Education, both teachers conveyed that the ability for teachers to personalize the word lists and images was important. In order to incorporate this feedback into our project, we built a web application that allows teachers to either select a premade list of words, or to upload their own words and images. Additionally, the website has instructions about how to operate the device and information about our team. This additional functionality makes our device more applicable in a classroom setting.

Costs

The cost to produce SpellCheck this semester was lower than the cost of one production model, as our team members already owned a MSP432 microcontroller. Table 6 shows a high-level breakdown of the total costs if SpellCheck was made in limited and large quantities.

	Cost for 1 unit	Cost per unit for 10,000 units
MSP432	$23.99	$4.26
PCB	$33	$5.75
PCB Components	$101.40	$58.24
LCD Display	$86.79	$34.20
Mounting Components	$19.40	$12.90
3D Printing Components	$35.96	$10
Magnets	$4.20	$3.30
Total	$304.74	$128.65

Table 6: SpellCheck Costs

The most expensive part of the system is the PCB and its components. If the project was scaled for mass production of 10,000 units, the total cost for one unit would decrease by 57.78%, from $304.74 to $128.65. To decrease costs in mass production, the 3D printed components could be manufactured with automated equipment instead of using 3D printers, which would significantly decrease the cost for the letter block pieces. Choosing a less expensive LCD display can also decrease costs for production. A detailed breakdown of all costs spent for SpellCheck, including testing materials, can be seen in Appendix D Figure 29.

Future Work

The team sought advice from professors from the UVA School of Education and Human Development in order to garner feedback and improvements of our system for practical use in the classroom environment. To improve upon the current version of SpellCheck, the team suggests that the project can be expanded in the following ways.

Dictation

Due to cost and timing constraints, we were not able to connect a speaker and dictate the objects for users to spell. This addition would eliminate any ambiguity of the objects displayed on the screen and help students connect the spoken word to its spelling. Professor Lysandra Cook and Professor Tisha Hayes emphasized the importance of phonics in spelling practice. Thus, incorporating a speaker that can sound out each letter as it is placed will help correlate the letters with their sounds. Sound would also be helpful for students who are visually impaired that want to use our system.

Advanced Blocks

Initially, the team believed that the number of unique combinations for identifying blocks was 31. After testing the magnets and assembling the letter blocks, we learned the polarity of the magnets mattered in the voltage reading from the sensor. Thus, the number of unique combinations for the blocks has increased to 242 (3^5) combinations. With these extra identifying combinations, blocks can be used to represent prefixes, suffixes, and digraphs. Blocks can also be used for shapes, numbers, and colors if teachers wanted to use the system's application for practice in another subject. In general, future teams should consider the variety of directions the system can be used in accordance with the different blocks that can now be produced.

Some modifications should also be made to the letter blocks. Professor Cook suggested the letter blocks have the letters in lowercase, as this would be of higher utility since platforms teachers use now are also in lowercase letters [45]. The current version of our system has uppercase letters due to cost and time restraints. The letter blocks could also incorporate the braille alphabet onto the blocks. This would make the system more inclusive for students who are visually impaired.

Gamification and Login

One aspect of our project that could be improved is the gamification and personalization of the system. Due to time constraints, the gamification on the LCD's interface was not as engaging as we had first expected. To improve the user experience, future teams should consider the time needed to develop the gamified user interface. In addition, future teams can also incorporate a user login for the device, so each student can have a personalized account where the teacher can then keep track of how the student is performing. Statistics each account could hold include the number of attempts per word and how many words were spelled correctly on the first try. According to Professor Tisha Hayes, this feature would be extremely useful for teachers to understand which areas their students need more help with.

Mounting Considerations

Future teams should be cognizant of assembly while developing designs for the system. For example, we match-drilled the PCB and slot panel in spaces available with no tracing, but the placement of the drilling could have been planned while designing the PCB beforehand. Planning for the holes would have resulted in a cleaner final look on the panel.

Incorporating Wifi Modules

One central feature of our device is the user interface that allows teachers to customize their own word lists and images. Currently, this uploading process requires a teacher to connect their laptop to the device via USB. However, this process is more involved and requires the teacher to be within a few feet of the device in order to upload new words. For ease of use, future teams may implement WiFi modules to allow teachers to interact with the device wirelessly. This feature would be much easier for teachers to use the SpellCheck device.

Collaboration with UVA School of Education and Human Development

In our meeting with Professor Lysandra Cook, we discussed putting our device in practice in a classroom environment. Professor Cook teaches reading and writing intervention, which is a course that examines reading and writing research and its implications for teaching students for disabilities, and offered an avenue to test our project in her class. Future teams may look into collaborating more closely with the UVA School of Education and Human Development and quantifying the true impact of the device in children aged 5-7.

References

[1] P. Tshering, D. Norbu, S. Dorji, N. Dema and P. Dhungyel, "Experience of a Gamified Spelling Solving by Students for Learning Spelling: Development of Kids Spell Dzongkha App," *International Conference on Current Trends towards Converging Technologies (ICCTCT),* pp. 1-5, 2018.

[2] G. Yolageldili and A. Arikan, "Effectiveness of using games in teaching grammar to young learners," *Elementary Education Online,* vol. 10, no. 1, pp. 219-229, 2011.

[3] N. Murphy, *A Multisensory vs. Conventional Approach to Teaching Spelling,* 1997.

[4] "myRIO-1900 User Guide and Specifications - National Instruments," p. 32.

[5] "MSP-EXP432P401R SimpleLink™ MSP432P401R high-precision ADC LaunchPad™ Development Kit," Texas Instruments, [Online]. Available: https://www.ti.com/store/ti/en/p/product/?p=MSP-EXP432P401R. [Accessed 10 December 2021].

[6] National Instruments, "Multisim," [Online]. Available: https://www.ni.com/enus/shop/software/products/multisim.html. [Accessed 15 December 2021].

[7] National Instruments, "Ultiboard," [Online]. Available: https://www.ni.com/enus/shop/software/products/ultiboard.html. [Accessed 15 December 2021].

[8] Texas Instruments, "CCSTUDIO_10.1.1.00004," [Online]. Available: https://www.ti.com/tool/download/CCSTUDIO. [Accessed 15 December 2021].

[9] Microsoft, "Visual Studio Code," [Online]. Available: https://code.visualstudio.com/. [Accessed 15 December 2021].

[1 "2 & 4 Layer PCB Special Pricing Options," Advanced Circuits, [Online]. Available: https://www.4pcb.com/pcb-prototype-2-4-layer-boards-specials.html. [Accessed 15 December 2021].

[1 M. Gajewski, *3D printers may be toxic to humans,* Forbes, 2020.

[1 J. Whiteaker and R. Gardham, *Opinion: Let's be honest, batteries are bad for the environment,* Investment Monitor, 2021.

[1 "What is ABS plastic and is it recyclable?," Plastic Collectors, 23 April 2020. [Online]. Available: https://www.plasticcollectors.com/blog/what-is-abs-plastic/. [Accessed 14 December 2021].

[1 IPC, *Generic Standard on Printed Board Design,* Northbrook, IL, 1998.

[1 IPC, *Acceptability of Printed Boards,* Northbrook, IL, 2010.

[1 JEDEC, *SMT / SMD Components & packages, sizes, dimensions, details.*

[1 All3DP, *STL File Format: Everything You Need to Know,* 2021.

[1 sparkfun, "Serial Communication: UARTs," [Online]. Available: https://learn.sparkfun.com/tutorials/serial-communication/uarts. [Accessed 15 December 2021].

[1 "SPI Tutorial," Corelis, [Online]. Available: https://www.corelis.com/education/tutorials/spi-tutorial/. [Accessed 15 December 2021].

[2 Barr Group, "Embedded C Coding Standard," Barr Group, [Online]. Available: https://barrgroup.com/embedded-systems/books/embedded-c-coding-standard. [Accessed 19 September 2021].

[2 "16 CFR § 1501 - METHOD FOR IDENTIFYING TOYS AND OTHER ARTICLES INTENDED FOR USE BY CHILDREN UNDER 3 YEARS OF AGE WHICH PRESENT CHOKING, ASPIRATION, OR INGESTION HAZARDS BECAUSE OF SMALL PARTS," Legal Information Institute, [Online]. Available: https://www.law.cornell.edu/cfr/text/16/part-1501. [Accessed 19 September 2021].

[2 *ASTM 963-17 Requirements,* Consumer Product Safety Commision.

[2 "16 CFR § 1505.5 - electrical design and construction.,"," Legal Information Institute, [Online]. Available: https://www.law.cornell.edu/cfr/text/16/1505.5. [Accessed 10 September 2021].

[2 "FreeDFM," Advanced Circuits, [Online]. Available: https://www.my4pcb.com/net35/FreeDFMNet/FreeDFMHome.aspx. [Accessed 15 December 2021].

[2 *WWW Electronics Incorporated,* Charlottesville, VA, 2021.

[2 "Fusion 360," Autodesk, [Online]. Available: https://www.autodesk.com/products/fusion-360/overview. [Accessed 15 December 2021].

[2 University of Virginia, *Rapid Prototyping Lab,* Charlottesville, VA, 2021.

[2 "VirtualBench," National Instruments, [Online]. Available: https://www.ni.com/en-us/shop/hardware/products/virtualbench-all-in-one-instrument.html. [Accessed 15 December 2021].

[2 "MSPDRIVERLIB," Texas Instruments, [Online]. Available: https://www.ti.com/tool/MSPDRIVERLIB. [Accessed 15 December 2021].

[3 R. Riedel, "FT800-FT813," [Online]. Available: https://github.com/RudolphRiedel/FT800-FT813. [Accessed 15 December 2021].

[3 "GitHub Documentation," [Online]. Available: https://www.google.com/url?q=https://docs.github.com/en&sa=D&source=docs&ust=1639589034990000&usg=AOvVaw0zGG5sdJYsVXRDxgzLSn6E. [Accessed 15 December 2021].

[3 "Git," [Online]. Available: https://www.google.com/url?q=https://git-scm.com/&sa=D&source=docs&ust=1639589034990000&usg=AOvVaw1qBxYSa98l4pQTdwxa7Rv9. [Accessed 15 December 2021].

[3 "JavaScript," MDN Web Docs, [Online]. Available: https://developer.mozilla.org/en-US/docs/Web/JavaScript. [Accessed 15 December 2021].

[3 "Cascading Style Sheets," [Online]. Available: https://www.w3.org/Style/CSS/Overview.en.html. [Accessed 15 December 2021].

[3 "React Native," [Online]. Available: https://reactnative.dev/. [Accessed 15 December 2021].

[3 "Vercel," [Online]. Available: vercel.com. [Accessed 15 December 2021].

[3 D. G. Wang, "Collective word building and spelling game". United States of America Patent US20080311546A1, 2007.

[3 허홍, "Block type board game using word alphabet puzzle for educational purpose". South Korea Patent KR20140130583A, 2013.

[3 陈利红, "A kind of English word spelling device". China Patent CN204440689U, 2015.

[4 "Drv5053raqlpg," DigiKey, [Online]. Available: https://www.digikey.com/en/products/detail/texas-instruments/DRV5053RAQLPG/5031907. [Accessed 10 September 2021].

[4 "LTC1390CS#PBF," Digi-Key, [Online]. Available: https://www.digikey.com/en/products/detail/analog-devices-inc/LTC1390CS-PBF/889886. [Accessed 15 December 2021].

[4 briancodex, "react-website-v1," [Online]. Available: https://github.com/briancodex/react-website-v1. [Accessed 15 December 2021].

[4 "Wooden ABC/123 Blocks," Melissa & Doug, [Online]. Available: https://www.melissaanddoug.com/wooden-abc%2F123-blocks/1900.html. [Accessed 15 December 2021].

[4 "Bower 360 Degree Phone Rotation Tripod Mount for Landscape and Portrait Mode, Black," Walmart, [Online]. Available: https://www.walmart.com/ip/Bower-360-Degree-Phone-Rotation-Tripod-Mount-for-Landscape-and-Portrait-Mode-Black/129337772?fulfillmentIntent=In-store. [Accessed 15 December 2021].

[4 "Digital Worlds Research," University of Florida, [Online]. Available: https://research.dwi.ufl.edu/op.n/file/gc8nkxns914enc7d/embed?fbclid=IwAR1OiYiB6fERCg-3wSWOPc0QZh4cmzyZ7wdO7f__fU2c4trzyanvj1xebko. [Accessed 15 December 2021].

[4 "ASTM 963-17 Requirements," Consumer Product Safety Comission, [Online]. Available: https://www.cpsc.gov/Business--Manufacturing/Business-Education/Toy-Safety/ASTM-F-963-Chart. [Accessed 19 September 2021].

[4 Toy Industry Association, "U.S. Safety Standards," The Toy Association, [Online]. Available: http://www.toyassociation.org/ta/advocacy/federal/standards/toys/advocacy/federal/us-safety-standards.aspx. [Accessed 10 September 2021].

[4 "Toys and Products Intended for Use By Children Under 3 Years Old," U.S. Consumer Product Safety Commission, [Online]. Available: https://www.cpsc.gov/s3fs-public/pdfs/foia_regsumsmallparts.pdf. [Accessed 19 September 2021].

Appendix

Appendix A

```
Binary|Decimal|Letter
------------
00001 = 1 = A
00010 = 2 = B
00011 = 3 = C
00100 = 4 = D
00101 = 5 = E
00110 = 6 = F
00111 = 7 = G
01000 = 8 = H
01001 = 9 = I
01010 = 10 = J
01011 = 11 = K
01100 = 12 = L
01101 = 13 = M
01110 = 14 = N
01111 = 15 = O
10000 = 16 = P
10001 = 17 = Q
10010 = 18 = R
10011 = 19 = S
10100 = 20 = T
10101 = 21 = U
10110 = 22 = V
10111 = 23 = W
11000 = 24 = X
11001 = 25 = Y
11010 = 26 = Z

26 letters
60 Magnets
```

Figure 27: Letter Encoding Scheme

Appendix B

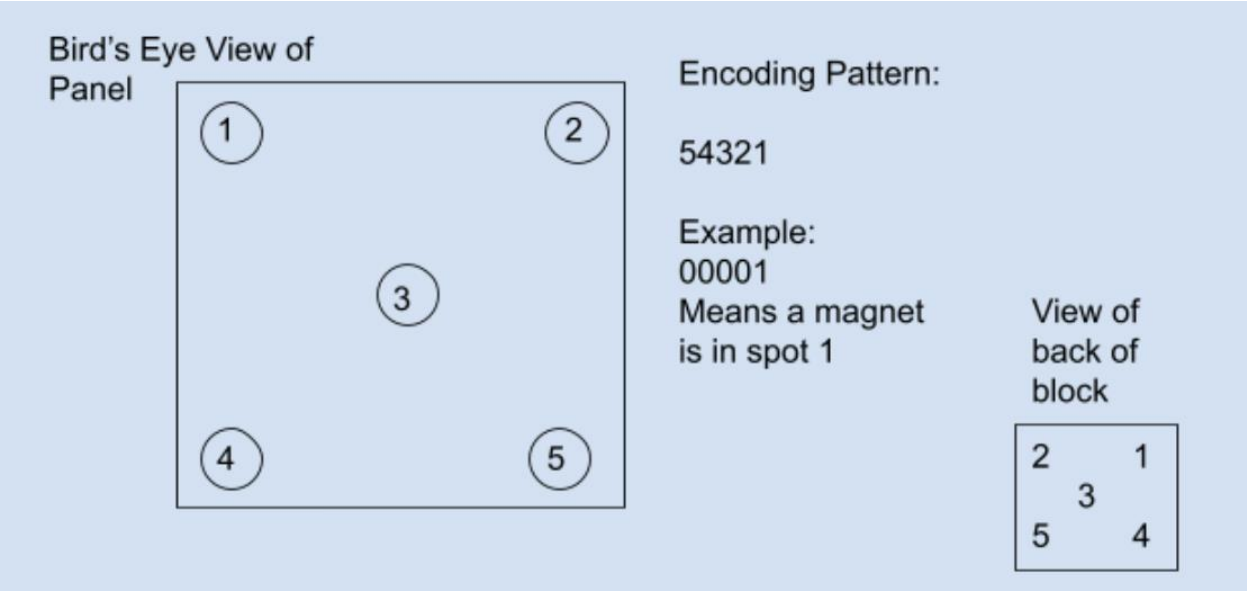

Figure 28: Magnet Assembly Reference

Appendix C

Status	Voltage Output #1	Voltage Output #2	Voltage Output #3	Average
No Magnet to Sensor	1.028	1.028	1.028	**1.028**
Magnet to Sensor (0 distance)	0.036	0.037	0.036	**0.036**
Magnet to Sensor + 1 Other Magnet (0.8in distance)	0.038	0.038	0.382	**0.153**
No Magnet to Sensor + 1 Other Magnet	1.031	1.031	1.030	**1.031**
No Magnet to Sensor + 2 Other Magnet	1.034	1.034	1.034	**1.034**
No Magnet to Sensor + 3 Other Magnet	1.028	1.032	1.029	**1.030**
No Magnet to Sensor + 4 Other Magnet	1.022	1.023	1.031	**1.025**
Magnet to Sensor + 1 Other Magnet	0.036	0.037	0.036	**0.036**
Magnet to Sensor + 2 Other Magnet	0.037	0.037	0.037	**0.037**
Magnet to Sensor + 3 Other Magnet	0.362	0.038	0.039	**0.146**

Table 7: Magnet Interference Testing

Appendix D

A	B	C	D	E	F	G
Item	Quantity	Unit Price	Total Cost	Remaining Budget		
				$500.00	Starting Budget	
8x1 Multiplexer	10	5.752	$57.52	$442.48		
Hall Effect Sensors	5	1.732	$8.66	$433.82		
LCD Display	1	86.79	$86.79	$347.03		
Connection Header	1	5.48	$5.48	$341.55		
AC/DC WALL MNT ADAPTER 12V 3.6W	1	9.84	$9.84	$331.71		
CONN PWR JACK 2X5.5MM SOLDER	1	1.37	$1.37	$330.34		
DC DC CONVERTER 3.3V 2W	1	7.83	$7.83	$322.51		
IDC CABLE - MKR20A/MC20G/MKR20A	1	4.91	$4.91	$317.60		
SWITCH PUSH SPST-NO 0.1A 32V	1	1.12	$1.12	$316.48		
Enclosure	1	18.71	$18.71	$297.77		
KJ Magnetics (Pack of 10)	3	1.1	$3.30	$294.47		
Female Connection Header	2	1.26	$2.52	$291.95		
				$291.95	Budget After Order#1	
Hall Effect Sensors	25	1.22	$30.50	$261.45		
Board SendOut #1	1	33	$33.00	$228.45		
				$228.45	Budget After Order#2	
PC TEST POINT	25	0.3408	$8.52	$219.93		
CONN HEADER VERT 6POS 2.54MM	10	0.227	$2.27	$217.66		
CAP ALUM 4.7UF 20% 50V RADIAL	10	0.138	$1.38	$216.28		
CAP CER 0.015UF 50V X7R RADIAL	50	0.0832	$4.16	$212.12		
CAP CER 0.1UF 50V X7R RADIAL	10	0.165	$1.65	$210.47		
CONN HEADER VERT 20POS 2.54MM	1	5.48	$5.48	$204.99		
CONN PWR JACK 2X5.5MM SOLDER	1	1.37	$1.37	$203.62		
DC DC CONVERTER 3.3V 2W	1	7.83	$7.83	$195.79		
CONN HDR 20POS 0.1 GOLD PCB	2	1.26	$2.52	$193.27		
				$193.27	Budget after Order#3	
KJ Magnetics (Pack of 10) 1/16x1/16	3	1.1	$3.30	$189.97		
KJ Magnetics (Pack of 10) 1/16 by 1/8	3	1.4	$4.20	$185.77		
PROTOBOARD 14/16 SOIC SMT SIP	2	5.62	$11.24	$174.53		
SENSOR HALL ANALOG SOT23-3	30	1.3944	$41.83	$132.70		
IC MULTIPLEXER 8X1 16SOIC	3	6.4	$19.20	$113.50		
CAP CER 10000PF 10V X7R 0805	30	0.133	$3.99	$109.51		
CAP CER 0.1UF 6.3V X7R 0805	10	0.151	$1.51	$108.00		
CAP CER 4.7UF 16V X7R 0805	3	0.64	$1.92	$106.08		
CABLE ASSEM 20POS	1	13.78	$13.78	$92.30	Budget after Order#4	
Board SendOut #2	1	33	$33.00	$59.30		
3D Printing - Letter Blocks	30	0.95	$28.50	$30.80		
3D Printing - Panel	1	7.46	$7.46	$23.34		
Miscellaneous for Assembly	N/A	N/A	$18.83	$4.51		
			Budget Remaining = $4.51			

Figure 29: SpellCheck Budget Breakdown

FDA Regulation of Artificial Intelligence in Medical Software

A Research Paper submitted to the Department of Engineering and Society

Presented to the Faculty of the School of Engineering and Applied Science
University of Virginia • Charlottesville, Virginia

In Partial Fulfillment of the Requirements for the Degree
Bachelor of Science, School of Engineering

Noah Beamon

Spring 2022

On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

Hannah Rogers, Department of Engineering and Society

FDA Regulation of Artificial Intelligence in Medical Software

Abstract

The analysis of multiple actors within a network demonstrates why CAD software continues to gain traction in modern healthcare notwithstanding its setbacks. This network consists of actors including congress and the Food and Drug Administration (FDA) which mitigate obscurities in the implementation of CAD software through documents such as the *Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan*. These mitigation efforts catalyze the continuity of CAD advancements driven by CAD software developers, physicians, and patients as additional actors within the network.

Cresswell employs actor-network theory (ANT) to identify multiple actors within a social network for characterizing the relationship between healthcare professionals and IT infrastructure (Cresswell). A similar approach is applied in this paper which observes that CAD advancements affect the healthcare industry by analyzing the social network between the FDA regulatory framework, physicians, patients, and CAD software engineers.

Suchman demonstrates that obscurities in artificial intelligence software result in discriminatory and indiscriminate targeting of individuals, while remaining politically and legally unaccountable (Suchman). This paper uses a similar approach. The FDA action plan is analyzed to demonstrate that the obscurities of CAD software application are sufficiently supervised by the FDA regulatory framework, remaining politically and legally accountable.

The FDA regulatory framework influences physicians, patients, and CAD software developers who rely on the FDA regulatory framework to properly use, understand, and improve the technology embedded in CAD software. They mitigate obscurities in CAD's usage and facilitate further development.

Introduction

In 2007, Dr. Robert Shmidt, a radiology professor at the University of Chicago told the *Chicago Tribune*, that patients "might choose a higher risk of an unnecessary biopsy in return for a better chance of finding a tumor" (Peres) while discussing the advantages of Computer Aided Diagnosis (CAD) software in light of its high false positive rate. Considering its high false positive rate, the effectiveness of the software regarding physicians using CAD to make diagnosis decisions, patients opting into the use of CAD, and the software functioning properly from a technical standpoint became a subject of debate. The comments sparked ongoing discourse regarding the efficacy of CAD and the growing machine learning (ML) and artificial intelligence (AI) applications in medicine which remains unresolved to this day. Nevertheless, in 2010, the National Library of Medicine reported the increasing use of CAD software in healthcare stating, "CAD was used in 70% of all screening mammographic studies, compared with 81% in private offices" (Rao). While it is evident that the efficacy of CAD software has been questioned throughout the past 20 years, medical professionals continue to rely on the technology giving the cutting-edge technology unparalleled currency in today's evolving healthcare environment. With sales of CAD software for breast imaging to raise 8.3% through 2025 (Singh), a comprehensive evaluation is necessary to determine the challenges this technology introduces.

The concept of Actor Network Theory (ANT) is applicable to the development of CAD; people and technology are actors performing in an interconnected network with dynamic relationships influencing each other. In evaluating the implications of CAD, the analysis of multiple actors within a network can be characterized to demonstrate why CAD software continues to gain traction in modern healthcare notwithstanding its apparent setbacks. This

network consists of actors including congress and the Food and Drug Administration (FDA) which seek to mitigate obscurities in the implementation of safe CAD software through documents such as the *Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan*. These mitigation efforts catalyze the continuity of CAD advancements driven by CAD software developers, physicians, and patients as additional actors within the network. This paper is not a holistic valuation of the CAD software industry and does not serve as a legal analysis of the FDA regulatory framework. Instead, this paper attempts to identify the underlying stakeholders that influence CAD software advancements; in doing so, it demonstrates how each of these stakeholders collaboratively facilitate CAD software advancements in the 21st century.

Identification of Actors and Algorithmic Equity

In *Actor-Network Theory and its role in understanding the implementation of information technology developments in healthcare*, Cresswell employs actor-network theory (ANT) to understand how advancements in Information Technology (IT) influence the healthcare infrastructure. The article defines an approach of identifying multiple actors within a social network for characterizing the relationship between healthcare professionals and IT infrastructure (Cresswell). A similar approach is applied in this paper which observes that CAD advancements affect the healthcare industry by analyzing the social network between the FDA regulatory framework, physicians, patients, and CAD software engineers.

In *Algorithmic warfare and the reinvention of accuracy*, Suchman analyzes U.S counterterrorism aerial surveillance programs and the U.S Department of Defense algorithmic warfare campaign Project Maven to demonstrate that obscurities in the applications of these artificial intelligence driven ventures result in discriminatory and indiscriminate targeting of

individuals, while remaining politically and legally unaccountable (Suchman). This paper uses a similar approach but in the context of medical application, and comes to a contrary conclusion regarding CAD. The *Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan* is analyzed to demonstrate that the obscurities of CAD software application are sufficiently supervised by the FDA regulatory framework resulting in nondiscriminatory and deterministic diagnoses, while remaining politically and legally accountable.

An Illustration of Actor Network Theory

To first understand how actor-network theory (ANT) can be applied to the continuous implementation and development of CAD software in healthcare environments, it is necessary to define ANT. ANT is a Science Technology and Society (STS) concept developed by Bruno Latour which aims to characterize the relationships between societal processes, objects, organizations, and individuals. Primarily, it suggests that processes, objects, organizations, and individuals are actors engaging in relationships that alter constantly changing networks. "ANT claims that modern societies cannot be described without recognizing them as having a fibrous, thread-like, wiry, stringy, ropy, capillary character that is never captured by the notions of levels, layers, territories, spheres, categories, structures, [and] systems" (Latour). ANT allows engineers to analyze systems as networks containing interconnected entities. In this manner, the CAD software industry, which is influenced by multiple entities including the FDA, physicians, patients, and software engineers can be analyzed. The FDA performs oversight to approve CAD while physicians, patients, and software engineers collaborate with the FDA and with each other to ensure CAD is used safely while improving CAD software. The collaboration between the FDA, physicians, patients, and software engineers alters the continuity of CAD software

advancements—changing how these actors collaborate alters the extent to which CAD advancements are introduced into health care.

ANT further implies that the relationships between actors are the only factors shifting the dynamics within the network. “ANT is a powerful tool to destroy spheres and domains, to regain the sense of heterogeneity, and to bring interobjectivity back into the centre of attention” (Latour). Therefore, processes, objects, organizations, and individuals are equally decisive in managing social dynamics within society. Latour claims:

> ANT has been developed by students of science and technology, and its claim is that it is utterly impossible to understand what holds society together without reinjecting in its fabric the facts manufactured by natural and social sciences and the artifacts designed by engineers (Latour).

Moreover, ANT serves as an effective STS framework for comprehensively evaluating the continuation of the CAD software industry in the 21st century because it involves the relationships between numerous administrative frameworks and individuals to facilitate its own continuity.

The FDA Regulatory Framework is the Gatekeeper

By using ANT as a framework for evaluating CAD software, numerous actors are eligible for evaluation. Given the predominance of bureaucracy in American government and democratic republics around the world, healthcare products and healthcare technologies are consistently regulated by governing agencies, commissions, and organizations. In *Why Is Health Care Regulation So Complex?* Field asserts, “Health care regulations are developed and enforced by all levels of government—federal, state, and local—and also by a large assortment of private organizations” (Field). Chiefly, in the United States the FDA “is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices” (FDA). The regulatory framework ensures the safety

of medical products such as CAD. The FDA is also responsible for "advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable" (FDA). Through the regulatory framework, the FDA influences industry by introducing limitations and facilitating expansion for medical device development. Therefore, it is necessary to recognize that the FDA is the gatekeeper within the network facilitating the relationships formed between additional, contributory actors within the network such as physicians, patients, and CAD software engineers who facilitate the continuity of CAD advancements directly.

CAD software is not legally available for commercial use unless the FDA approves it through a regulatory process. In *Concepts in U.S. Food and Drug Administration Regulation of Artificial Intelligence for Medical Imaging*, Kohli states, "Regardless of the task for which it is used, AI, like drugs and devices, will be regulated by the U.S. Food and Drug Administration (FDA)" (Kohli). The rapidly developing field of AI and ML in medical products presents unforeseen regulatory challenges that have not been addressed until recently; because modern CAD software implements AI and ML, the regulation that oversees its development is volatile. In January 2021 the FDA released the *AI/ML-based SaMD Action Plan* stating:

> In light of the public health need to facilitate innovation through AI/ML-based medical software while providing appropriate oversight for it, and consistent with the mission of the newly launched Digital Health Center of Excellence, the Agency is presenting this AI/ML-Based Software as a Medical Device Action Plan. In this document, we will briefly summarize the feedback we have received from stakeholders in this area, and we will briefly describe a five-part Action Plan to advance this work (FDA).

This document serves as a foundation for characterizing the relationship between the FDA and the numerous actors within the network that also facilitate CAD advancements.

Through the FDA's regulatory framework established in the *AI/ML-based SaMD Action Plan*, how the FDA formulates its relationships between physicians, patients, and software engineers is prevalent. In establishing this regulatory framework, obscurities in CAD implementation are minimized. The document addresses four paramount areas of interest for the development and risk mitigation of CAD software which are intended to facilitate CAD advancements: 1) tailored regulatory framework for AI/ML-based SaMD, 2) good machine learning practice (GMLP), 3) patient-centered approach incorporating transparency to users, and 4) regulatory science methods related to algorithm bias and robustness.

Tailored Regulatory Framework for AI/ML-based SaMD

The first area of interest that allows the FDA to effectively establish a foundation for regulating AI and ML in software is the development of a custom-made approach for documenting the specific use of AI and ML in the product. The FDA relies on change control plans in order to succinctly define the use of AI in a medical software. These plans include information regarding the anticipated modifications and associated methodology used to implement those changes in a controlled manner; in particular, they characterize the aspects of the software that are intended to change throughout the algorithm learning and how the algorithm will learn and change depending on the inputs (FDA). For CAD software engineers, this aspect of the regulatory framework requires a distinct description of the different aspects of the software that change. CAD engineers must also demonstrate how medical images analyzed by the system affect the system and its outputs. CAD engineers are actors facilitating the advancements of CAD software by documenting the technological aspects of CAD. The process of documentation helps guide further FDA rule making procedures related to AI/ML in medical software.

There are two FDA documentation processes that allow for the pure specification and compliance of software such as CAD: 1–SaMD Pre-Specifications (SPS) and 2–Algorithm Change Protocol (ACP). The *AI/ML-based SaMD Action Plan* states:

> The discussion paper proposed a framework for modifications to AI/ML-based SaMD that relies on the principle of a "Predetermined Change Control Plan." As discussed above, the SaMD Pre-Specifications (SPS) describe "what" aspects the manufacturer intends to change through learning, and the Algorithm Change Protocol (ACP) explains "how" the algorithm will learn and change while remaining safe and effective (FDA).

Evidently, the FDA regulatory framework influences CAD software engineers by encouraging them to develop safe and effective software, requiring them to clearly document this information for approval. In *Computer aided detection (CAD): an overview,* Castellino states, "More recently, computer programs have been developed and approved for use in clinical practice that aid radiologists in detecting potential abnormalities on diagnostic radiology exams" (Castellino) indicating that there are scopes to which the software is approved for usage and not approved for usage. While the use of CAD to analyze mammographic images is approved, using CAD in medical specialties outside of mammography is not approved.

In defining the SPS for CAD software, software engineers define the aspects of the software that change through the machine learning process which guides the decision making in the software. Castellino argues, "The CAD algorithms require a digital data set of the image for analysis. If the image is acquired on x-ray film, such as a film-screen mammogram, the analog image must first be digitized" (Castellino). Digital images are obtained in order to train the system to recognize abnormalities when an image is entered as an input for diagnosis.

When defining the ACP for CAD software, software engineers define the aspects of the software that learn and change while also maintaining safety and efficacy. The regulation of

CAD software in this aspect is significantly difficult because a component of its safe operation depends on the user. In *Computer-Aided Diagnosis in Medical Imaging: Historical Review, Current Status and Future Potential*, Doi claims, "with CAD, radiologists use the computer output as a "second opinion" and make the final decisions. CAD is a concept established by taking into account equally the roles of physicians and computers" (Doi). Therefore, a component of CAD's safety and efficacy depends on the physician using it.

While AI and ML implementations in the software are intended to operate safely, it is apparent that physicians are still responsible for the safety of their patients when using the software because of technical limitations. While discussing the detection of clustered microcalcifications by a CAD software licensed to a company in 1993, Doi states, "the previous performance level [was] 87% sensitivity at 1.0 false positive per image with an estimated current performance level [of] 98% sensitivity at 0.25 false positive per image of the latest commercial CAD system" (Doi). Clearly, although CAD is an effective tool for physicians, physicians must recognize its technical limitations and recognize when it underperforms, especially in the instance of a false positive result. Physicians' contributions within the network driving CAD development are therefore responsible for facilitating the technical advancements in CAD because they are an element within the network whose responsibility is to maintain safety and efficacy.

Good Machine Learning Practice (GMLP)

The second area of interest that allows the FDA to effectively regulate and advance the safe development of AI/ML driven products is the dynamic development of a list of practices all software engineers developing CAD products can follow. This process establishes a set of

precise, standardized instructions for software engineers to follow when developing CAD systems and other AI/ML driven products (GMLP). The *AI/ML-based SaMD Action Plan* states:

> Development and adoption of these practices is important not only for guiding the industry and product development, but also for facilitating oversight of these complex products, through manufacturer's adherence to well established best practices and/or standards (FDA).

Developing GMLP helps the FDA succinctly guide industry standards to facilitate the efficacy of CAD software.

Software engineers adhering to GMLP are able to directly advance CAD performance because safety standards and suggested practices are predefined—developers can focus solely on developing algorithms for identifying abnormalities in images and maintain security, safety, and efficacy. For example, convolutional neural networks (CNN) are a common neural network in modern CAD systems used to train the software to recognize abnormalities in medical images. CAD software engineers perform numerous testing and verification procedures on CNNs in order to maintain system efficacy in compliance with GMLP. In *Testing and verification of neural-network-based safety-critical control software: A systematic literature review,* Zhang while discussing CNN safety protocols software engineers developing safety-critical software such as CAD should follow, says, "improving the failure resilience of NNs [(neural networks)], measuring and ensuring test completeness, assuring safety properties of NN-based control software, and improving the interpretability of NNs [are] crucial. . .in safety-critical applications" (Zhang). Furthermore, significant research indicates that these safety protocols are helping CAD software engineers improve the safety of CAD each year. In *Quantifying the uncertainty of deep learning-based computer-aided diagnosis for patient safety* Laves states:

> A recent study established a diagnostic classifier based on convolutional neural networks (CNN), which was trained on a large database of more than 84,000 retinal OCT images of four different disease states. The performance in

> classifying retinal conditions was comparable to that of trained physicians. Equipped with deep neural networks, mobile assistance systems can extend the reaching of ophthalmologists in the field and increase access to medical care (Laves).

In this discussion of the AI/ML test and verification procedures addressed by Zhang, it is evident that standardized procedures when followed by CAD software developers reduce the uncertainty of CAD systems. Moreover, Laves' article shows that developing GMLP based standards is improving the efficacy of CAD software. By following GMLP outlined by the FDA, CAD software engineers are able to develop more effective CAD systems and reduce their uncertainty catalyzing CAD software advancement. CAD software engineers serve as actors within the network promoting new safety related procedures for implementation in the FDA regulatory framework. The FDA is a gatekeeping actor overseeing and implementing the standardized safety procedures under the GMLP agenda.

Patient-Centered Approach Incorporating Transparency to Users

The third area of interest that allows the FDA to regulate CAD and influence additional, contributory actors within the network driving CAD advancements is a patient-centered approach that is grounded in providing transparency to CAD users. According to the *AI/ML-based SaMD Action Plan*:

> We intend to consider this input for identifying types of information that FDA would recommend a manufacturer include in the labeling of AI/ML-based medical devices to support transparency to users. These activities. . .support the transparency of and trust in AI/ML-based technologies (FDA).

Because physicians are the users of CAD, the FDA suggests CAD software engineers supply them with supplemental materials containing information related to how the device works and what its intended purposes are. Additionally, the action plan claims, "the Agency is committed to supporting a patient-centered approach including the need for a manufacturer's transparency to

users about the functioning of AI/ML-based devices to ensure that users understand the benefits, risks, and limitations of these devices" (FDA). Patients are actors within the network that must agree to the use of the software—patients using CAD facilitate its continuity of advancement in health care by allowing for further research of CAD and its direct application in medicine. The FDA serves as an actor within the network facilitating physicians' understanding of the product by ensuring they are well informed regarding the capabilities of CAD software.

By ensuring physicians are informed regarding CAD's advantages and disadvantages, patients are also well-informed. In the clinical environment, physicians are able to properly explain to patients how CAD works and what the results of a CAD diagnosis indicate. In *Computer-Aided Diagnosis in Medical Imaging: Historical Review, Current Status and Future Potential*, Doi states,

> patients in most advanced countries would not be able to accept a lower level of diagnostic results by computer than the average level achievable by physicians. In addition, the reimbursement for the cost of an automated computer diagnosis may be refused by insurance companies (Doi).

Doi suggests patients who currently receive treatment involving a CAD diagnosis without a physician present outside the U.S should receive additional information regarding the meaning of the diagnosis given the unreliability of some CAD systems. Contrastingly, he asserts that CAD software advancements are also driven by insurance companies implying CAD software must be effective and accurate enough for insurance companies to pay for treatment resulting from a positive CAD diagnosis. Both of these factors are reasonable elements for consideration when determining the broader effect patients have on the network that facilitates CAD software advancements. Patients must be able to trust the CAD software and be able to pay for its usage and any subsequent treatments.

Additionally, the FDA's patient-centered approach benefits from transparency between CAD software engineers and patient advocacy groups. In *Computer-aided Diagnosis: How to Move from the Laboratory to the Clinic*, van Ginneken states:

> Radiologists, as workstation users, together with patient advocacy groups and regulatory agencies, should insist that vendors allow such interoperability and embrace open standards. Workstation vendors should realize that their product has more value if it allows integration of any CAD product, even a product from a competitor (van Ginneken).

The FDA's plan for establishing transparency to users encourages CAD software engineers from competing entities to collaborate. This collaboration allows multiple CAD software manufacturers to deliver the best product to physicians and patients—manufacturers are able to ensure and publicize that their product is state of the art. Furthermore, the FDA's facilitation of transparency between physicians and patients and between CAD software engineers allows the continuity of CAD in clinical practice. Patients as contributory actors within the network are able to make a well-informed decision regarding the use of the software and trust its capabilities.

Regulatory Science Methods Related to Algorithmic Bias & Robustness

The fourth area of interest that allows the FDA to regulate CAD and influence additional, contributory actors within the network driving CAD advancements is regulatory science methods related to algorithmic bias and robustness. The *AI/ML-based Action Plan* states:

> Because AI/ML systems are developed and trained using data from historical datasets, they are vulnerable to bias – and prone to mirroring biases present in the data. Health care delivery is known to vary by factors such as race, ethnicity, and socio-economic status; therefore, it is possible that biases present in our health care system may be inadvertently introduced into the algorithms (FDA).

In the context of CAD software engineering, CAD software algorithms are vulnerable to bias based on the historical datasets that train their machine learning models. CAD software engineers can reduce this vulnerability by developing methods for reducing the potential biases. The *AI/ML-based Action Plan* elaborates on this notion:

> The Agency recognizes the crucial importance for medical devices to be well suited for a racially and ethnically diverse intended patient population and the need for improved methodologies for the identification and improvement of machine learning algorithms. This includes methods for the identification and elimination of bias, and on the robustness and resilience of these algorithms to withstand changing clinical inputs and conditions (FDA).

Furthermore, by establishing regulations that promote methods for reducing bias in medical software, software engineers as contributory actors are motivated to establish technical strategies to make their software equitable.

While discussing medical software Gonçalves argues that although medical device software engineers may have good intentions, their work may be detrimental. In *LLM in Law & Technology Tilburg Law School Tilburg University August 2018* Gonçalves states, "one of the risks associated with the performance of machine learning within diagnosis and choice of treatment is the possible bias of the data collected and afterwards inserted in the machine" (Gonçalves). CAD software engineers must ensure the software is comprehensive in its adaptation to all patients in compliance with this FDA's concern; the technological advancements they employ show they are addressing this issue. For example, Larrazabal, a CAD software researcher, in *Gender imbalance in medical imaging datasets produces biased classifiers for computer-aided diagnosis*, states "Our study shows that gender imbalance in medical imaging datasets produces biased classifiers for computer-aided diagnosis based on convolutional neural networks (CNNs), with significantly lower performance in

underrepresented groups" (Larrazabal). When addressing the FDA regulatory framework, she advocates for better methods that reduce algorithmic gender bias in minority groups stating:

> As an example, let us take the US Food and Drug Administration. Even though they have released several documents related to the importance of gender/sex issues in the design and evaluation of clinical trials and medical devices, when looking at the specific guidelines to obtain the certification to market medical computer-aided systems, there is no explicit mention of gender/sex as one of the relevant demographic variables that should describe the sampled population (Larrazabal).

Clearly, as the FDA has motivated CAD software engineers to address bias; CAD software engineers themselves have proposed changes and conceptual and technical solutions to ensure CAD systems are equitable. In this manner, CAD software engineers are additional, contributory actors motivated by the FDA regulatory framework to make meaningful advancements in CAD performance; as a result, the FDA framework is continuously adjusted to account for these advancements.

Counterarguments & Objections

While this paper argues that the continuity of CAD software advancements in clinical practice is facilitated by the FDA regulatory framework influencing additional actors, there are two alternate perspectives for understanding the continued use and development of CAD software throughout the 21st century. The first counterargument suggests that CAD software advancements are exclusively a result of comprehensive technological advancements in the field of computer engineering. The second counterargument implies that the FDA's ineffectiveness and difficulty in regulating CAD software is facilitating the advancements of CAD and its continued use. While both of these alternate positions may hold validity in a limited scope, they are broad generalizations regarding a very complex, emerging industry where AI and ML are just a subcomponent of a larger collaborative infrastructure.

It is apparent that the first counterargument may be more relevant for identifying the reason behind the growth of AI and ML as a whole; it does not address the specific use case of AI and ML in medical software. While discussing the emergence of CAD software during recent years in *Computer-Aided Diagnosis in the Era of Deep Learning*, Chan states:

> The availability of low-cost graphical processing units (GPUs) and memory from the video gaming industry makes it possible to use CNN with a large number of layers and kernels. The fast internet and cloud facilitate the collection of large data samples for training (Chan).

While this observation is definitely relevant for understanding the improvements in software implementing machine learning and artificial intelligence, it does not specifically acknowledge the additional bureaucratic, regulatory advancements that are necessary for the continuation of CAD software applications in health care environments. This argument serves as a purely technical solution to a problem that also has an overarching social, legal, and legislative component.

The second counterargument does not only disregard the social, political component of the CAD industry; it also assumes the FDA has an overwhelming sphere of influence in health care. In *Computer-aided diagnosis in medical imaging: Review of legal barriers to entry for the commercial systems*, Lin argues,

> We noticed expansion of regulatory definition and variation of device classes and product codes among CAD systems with similar clinical uses, which may compromise the efficacy of such regulatory controls. The results suggested ineffectiveness of current premarket regulatory controls for CAD systems in the United States (Lin).

This argument does not consider the current regulatory foundations the FDA has committed to in terms of regulating AI and ML in medical software. It ultimately reduces the issue to private sector self-regulation. While the private sector does regulate CAD software on its own, the FDA

collaborates with CAD software stakeholders to legalize the use of CAD software in a clinical setting.

ANT comprehensively addresses the issue from all facets– technical, social, and political. It provides an explanation for the relationship of CAD technical advancements with respect to non-technical stakeholders, to show the FDA regulatory framework influences physicians, patients, and CAD software developers which facilitates the continuity of CAD in health care environments.

Conclusion

Overall, multiple actors within a network can be characterized to demonstrate why CAD software continues to gain traction in modern healthcare notwithstanding its setbacks. The FDA regulatory framework influences physicians, patients, and CAD software developers who rely on the FDA regulatory framework to properly use, understand, and improve the technology embedded in CAD software. Likewise, the FDA regulatory framework relies on physicians, patients, and CAD software engineers as stakeholders in order to modify its policy of medical software integrating AI and ML. These adjustments have a direct impact on CAD software. They mitigate obscurities in CAD's usage and ultimately facilitate further development. Although the resulting network is progressive in facilitating technological advancements, it is comprehensively a stable network. The FDA regulatory framework for AI/ML in medicine is likely to continue to change in the future as medical software implementing AI/ML become more advanced. However, the FDA will always be a gatekeeper facilitating the advancements of CAD with physicians, patients, and CAD software developers serving as additional actors; the network is unlikely to change. This dynamic in the network can only change through congressional legislation in support of the medical software industry regulating itself. Greater self-regulation

within the medical software industry would give physicians, patients, and CAD software developers more power over the regulation of AI/ML in medical software without additional FDA oversight.

References

Castellino, R. A. (2005). Computer aided detection (CAD): An overview. *Cancer Imaging*, *5*(1), 17–19. https://doi.org/10.1102/1470-7330.2005.0018

Chan, H.-P., Hadjiiski, L. M., & Samala, R. K. (2020). Computer-Aided Diagnosis in the Era of Deep Learning. *Medical Physics*, *47*(5), e218–e227. https://doi.org/10.1002/mp.13764

Chen, M. M., Golding, L. P., & Nicola, G. N. (2021). Who Will Pay for AI? *Radiology: Artificial Intelligence*, *3*(3), e210030. https://doi.org/10.1148/ryai.2021210030

Commissioner, O. of the. (2021, June 28). *What We Do*. FDA; FDA. https://www.fda.gov/about-fda/what-we-do

Cresswell, K. M., Worth, A., & Sheikh, A. (2010). Actor-Network Theory and its role in understanding the implementation of information technology developments in healthcare. *BMC Medical Informatics and Decision Making*, *10*(1), 67. https://doi.org/10.1186/1472-6947-10-67

Doi, K. (n.d.). *Computer-Aided Diagnosis in Medical Imaging: Historical Review, Current Status and Future Potential*. Retrieved November 9, 2021, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1955762/

Field, R. I. (2008). Why Is Health Care Regulation So Complex? *Pharmacy and Therapeutics*, *33*(10), 607–608.

Gonçalves, M. A. (n.d.). *LLM in Law & Technology Tilburg Law School Tilburg University August 2018*. 75.

Health, C. for D. and R. (2021). Artificial Intelligence and Machine Learning in Software as a Medical Device. *FDA*. https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device

Kohli, A., Mahajan, V., Seals, K., Kohli, A., & Jha, S. (2019). Concepts in U.S. Food and Drug Administration Regulation of Artificial Intelligence for Medical Imaging. *AJR. American Journal of Roentgenology*, *213*(4), 886–888. https://doi.org/10.2214/AJR.18.20410

Larrazabal, A. J., Nieto, N., Peterson, V., Milone, D. H., & Ferrante, E. (2020). Gender imbalance in medical imaging datasets produces biased classifiers for computer-aided diagnosis. *Proceedings of the National Academy of Sciences*, *117*(23), 12592–12594. https://doi.org/10.1073/pnas.1919012117

Latour, B. (1996). *On actor-network theory: A few clarifications*. 369–381.

Laves, M.-H., Ihler, S., Ortmaier, T., & Kahrs, L. A. (2019). Quantifying the uncertainty of deep learning-based computer-aided diagnosis for patient safety. *Current Directions in Biomedical Engineering*, *5*, 223–226. https://doi.org/10.1515/cdbme-2019-0057

Lin, T.-W., Huang, P.-Y., & Cheng, C. W.-C. (2016). Computer-aided diagnosis in medical imaging: Review of legal barriers to entry for the commercial systems. *2016 IEEE 18th International Conference on E-Health Networking, Applications and Services (Healthcom)*, 1–5. https://doi.org/10.1109/HealthCom.2016.7749517

Peres, J. (n.d.). *Mammogram study faults computer screening*. Chicago Tribune. Retrieved February 5, 2022, from https://www.chicagotribune.com/news/ct-xpm-2007-04-05-0704050197-story.html

Rao, V. M., Levin, D. C., Parker, L., Cavanaugh, B., Frangos, A. J., & Sunshine, J. H. (2010). How widely is computer-aided detection used in screening and diagnostic mammography? *Journal of the American College of Radiology: JACR*, *7*(10), 802–805. https://doi.org/10.1016/j.jacr.2010.05.019

Realizing the promise: How can education technology improve learning for all? (2020,

September 10). *Brookings*. https://www.brookings.edu/essay/realizing-the-promise-how-can-education-technology-improve-learning-for-all/

Singh, M. (n.d.). *Computer-Aided Detection Market to Benefit from Increasing Adoption of Tomosynthesis, Exhibiting Growth at 9.8% CAGR through 2025*. BioSpace. Retrieved February 5, 2022, from https://www.biospace.com/article/computer-aided-detection-market-to-benefit-from-increasing-adoption-of-tomosynthesis-exhibiting-growth-at-9-8-percent-cagr-through-2025/

Software As a Medical Device: FDA Digital Health Regulation. (n.d.). Deloitte United States. Retrieved April 11, 2022, from https://www2.deloitte.com/us/en/pages/public-sector/articles/software-as-a-medical-device-fda.html

Suchman, L. (2020). Algorithmic warfare and the reinvention of accuracy. *Critical Studies on Security*, *8*(2), 175–187. https://doi.org/10.1080/21624887.2020.1760587

Thomas, L. G. (1988). Revealed Bureaucratic Preference: Priorities of the Consumer Product Safety Commission. *The RAND Journal of Economics*, *19*(1), 102–113. https://doi.org/10.2307/2555400

van Ginneken, B., Schaefer-Prokop, C. M., & Prokop, M. (2011). Computer-aided Diagnosis: How to Move from the Laboratory to the Clinic. *Radiology*, *261*(3), 719–732. https://doi.org/10.1148/radiol.11091710

Zhang, J., & Li, J. (2020). Testing and verification of neural-network-based safety-critical control software: A systematic literature review. *Information and Software Technology*, *123*, 106296. https://doi.org/10.1016/j.infsof.2020.106296

Prospectus

SpellCheck: An Educational Device to Improve Children's Spelling

FDA Regulation of Artificial Intelligence in Medical Software

A Thesis Prospectus
In STS 4500
Presented to
The Faculty of the
School of Engineering and Applied Science
University of Virginia
In Partial Fulfillment of the Requirements for the Degree
Bachelor of Science in Computer Engineering

By
Noah Beamon

November 1, 2021

Technical Team Members:
Justin Guo, Rachel Lew, Catlinh Nguyen, Shymbolat Tnaliyev

On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

ADVISORS

Hannah Rogers, Department of Engineering and Society

Harry Powell, Electrical and Computer Engineering

Overview

This prospectus comprises an abstract of a Science, Technology & Society (STS) project and a pre-approved technical project addressing two distinct areas of interest: bureaucratic regulation of artificial intelligence integrated software used in health care environments and gamification in youth educational devices, respectively. The overall scope examines the significance of each area of interest, related research questions, sources, research planning, and the importance of results for each project.

STS Project

Introduction

The implementation of computer software to facilitate the storage, supervision, and reporting of medical images is an established utility of today's healthcare environment. In *Computer Aided Detection (CAD): An Overview*, Castellino states, "the use of computers to help radiologists in the acquisition (e.g. CT, MRI, US, computed radiography), management and storage (PACS), and reporting (RIS) of medical images is well established." According to *Computer-Aided Diagnosis in Medical Imaging: Historical Review, Current Status and Future Potential*, Doi asserts, "serious and systematic investigation on CAD began in the 1980s with a fundamental change in the concept for utilization of the computer output, from automated computer diagnosis to computer-aided diagnosis."

While early CAD software incorporated non-intensive algorithms applying a limited scope of artificial intelligence and machine learning (AI/ML), 21st century CAD software development intensively relies on AI and ML to facilitate more comprehensive evaluations of medical images. The authors of *Artificial intelligence, machine learning, computer-aided*

diagnosis, and radiomics: advances in imaging towards to precision medicine assert that "With the advent of artificial intelligence and 'big data', we are moving toward reducing . . . limitations, homogenizing and expanding the use of CAD tools in [the] daily routine of physicians." Twenty-first century advancements have improved the efficacy of detecting malignancies in medical images, but must be properly regulated. In particular the U.S Food and Drug Administration (FDA) must ensure the safety of CAD software in a capacity unforeseen in prior years.

The significance of this topic is twofold: first-- 21st century FDA regulation must appropriately supervise the prevalence of AI and ML driven strategies in CAD software to protect public health; second—overly restrictive FDA regulation applicable to AI and ML medical applications' software can adversely affect their development. Moreover, understanding how recent FDA plans facilitate and restrict the development of CAD software requires comprehensive evaluation of the socio-technical relationship between the FDA regulatory framework and AI driven medical software development. In her discussion of *Algorithmic Warfare and the Reinvention of Accuracy*, Suchman suggests "developments in the automation of data analysis… increasingly obscures more than it reveals." She implies that as technology becomes more complex, obscurities they introduce into society and the daily use of intended users become more abundant. Accordingly, characterizing CAD and the potential obscurities it imposes through the automated observation of medical images requires the illustration of the relationship between the FDA regulatory framework and CAD software development. Evidently, the STS framework of actor network theory can be applied to characterize this relationship. "ANT [(actor network theory)] is a powerful tool to destroy spheres and domains, to regain the sense of heterogeneity, and to bring interobjectivity back into the centre of attention" (Latour).

Using actor network theory, the implementation of CAD software will be analyzed as a network. This network consists of actors including congress and the FDA which seek to mitigate obscurities in the implementation of safe CAD software. These mitigation efforts catalyze the continuity of CAD advancements driven by CAD software developers, physicians, and patients as secondary actors within the network.

Research Question

How does the FDA's *Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan* influence advancements in computer aided diagnosis software (CAD)?

Research Method

Actor network theory is utilized to evaluate the FDA action plan, which states, "This AI/ML-Based Software as a Medical Device Action Plan was developed in direct response to the stakeholder feedback described herein, and it builds on the Agency's longstanding commitment to support innovative work in the regulation of medical device software."

FDA action plan influences advancements in computer aided diagnosis in two ways: one—initiatives that encourage the innovation of CAD and two—initiatives that restrict CAD development. *Concepts in U.S. Food and Drug Administration Regulation of Artificial Intelligence for Medical Imaging* asserts, "By creating novel regulatory pathways, the FDA is encouraging the adoption of AI in medicine." Additionally, the current FDA action plan restricts CAD development. In *FDA Review Can Limit Bias Risks in Medical Devices Using Artificial Intelligence*, Richardson claims, "calling out potential disparities on product labels, and pushing internally for the prioritization of equity in its review process, FDA can prevent potentially

biased products from entering the market." Recognizing this dichotomy presented by a regulatory framework that both acts as a catalyst and inhibitor for CAD software development is the first and perhaps most important method for answering the research question as it pertains to actor network theory.

Secondly, characterizing the scope of software the current FDA action plan comprises is a significant factor in the relationship characterized by actor network theory. It is evident that FDA regulations neither sufficiently or insufficiently regulate CAD software definitively. In *New Developments in FDA Regulation of AI* Thompson states:

> the guidance sums up the test by explaining: 'A practitioner would be unable to independently evaluate the basis of a recommendation [by CAD], and therefore would be primarily relying upon it'…Unfortunately, FDA took a step backward by declaring that transparency only applies to the lowest risk category of CDS [(clinical decision support)] software, a position found nowhere in the federal statute. Several organizations pointed that out in comments submitted on the September proposal. We have not seen a final guidance.

Defining the scope to which the 2021 action plan applies to CAD software is a source of insight for evaluating how 2021 FDA initiatives influence CAD advancements.

Finally, an analysis of the obscurities that CAD software introduces to the FDA regulatory framework and the daily routine of physicians who use CAD software must be observed using actor network theory to answer the research question. Understanding how CAD software has introduced regulatory obscurities provides insight for future action plans. Additionally, understanding the obscurities that physicians experience while using CAD software is notable. *Liability arising from the use of Artificial Intelligence for the purposes of medical diagnosis and choice of treatment: who should be held liable in the event of damage to health?* states, "This technology has indeed triggered the debate over how misdiagnosis and wrong plan treatments (chosen in light of the output of the algorithm) must be addressed under

the liability regimes currently in force" (Gonçalves). The actor network framework helps us understand the current challenges of CAD regulation and CAD implementation. This framework will demonstrate the reliance the FDA and CAD software development have on each other in mitigating obscurities.

Conclusion

The FDA's action plan addressing AI driven medical software and its effect on CAD software development will be determined through the evaluation of the relationship between the FDA regulatory framework and CAD medical software development using actor network theory. Sources containing quantitative figures and previous research findings will be presented to establish results. These results will reinforce the ongoing expectation that bureaucracy can concurrently protect public health and facilitate AI integrated medical software advancements notwithstanding the obscurities they introduce in health care environments.

Technical Project

Introduction

Early 21st century advancements of software in the children's toy industry are indicative of an emerging market in youth education-- gamification. Gamification is the application of typical elements of game playing to other areas of activity to encourage engagement with a product or service. Gamification in youth education is now a paramount tool that facilitates child development during the learning process (Dicheva). Throughout the American education system, gamification is implemented at numerous levels to incorporate educational activities that not only support a child's grasp of paramount skills but also a child's social emotional learning (Williamson). To evaluate the effectiveness of gamification in youth education, our team is

developing SpellCheck, an educational device which prompts a child to place individual letters in a machine to spell the name of an object that appears on a screen.

The development of SpellCheck allows for the thorough evaluation of specific skills that children can gain through devices that implement gamification. Additionally, the development of this device allows for education professionals to analyze how gamification learning affects youth social emotional learning skills. Overall, understanding gamification in educational devices and how it influences learning and social emotional skills in youth is important because it facilitates the effective development of future learning devices.

Research Question

How do game-based learning devices influence the development of 5 - 7-year-old children?

Research Method

Gamification in educational devices is most effective in youth who receive special education support, and less effective for students who receive general education support. *The Impact of Game-Based Learning in a Special Education Classroom* suggests that game-based learning devices in special education keep students "focused on their work" with a "positive attitude" (James). *Playing in the special education school: from gamers to game designers* reinforces this concept stating that students are "motivated and focused much more than they usually are" (Saridaki). Moreover, learning strategies and devices implementing a game format significantly influence learning in classrooms.

The major assumption in this project is that game-based learning devices are beneficial to the learning and development of all skills. This research does not consider whether some

classroom lessons and skills are taught better without using a game-based learning approach. Technical research in this area follows a strategy that develops a game with learning objectives embedded. Researchers then analyze the impact that the game had on child development in a focus group. *Investigating the Learning Impact of Game-based Learning when Teaching Science to Children with Special Learning Needs* suggests that the results of research in game-based learning tools for science can be applied for other academic skills (Mawes). A similar proposal is made in *Effective Learning Design of Game-Based 3D Virtual Language Learning Environments for Special Education Students;* the authors suggest that the benefits of a game-based learning approach used to teach special education students how to learn a foreign language are conterminous to the benefits seen in game-based learning devices targeting other skills (Lan).

This project will comprise the development of a device which implements game-based learning. We will evaluate the effectiveness of the device by performing focus group evaluations and observations in local public schools. The results will reinforce insight into how technological devices can be used in the classroom to facilitate learning.

References

Suchman, Lucy. "Algorithmic Warfare and the Reinvention of Accuracy." *Critical Studies on Security* 8, no. 2 (May 3, 2020): 175–87. https://doi.org/10.1080/21624887.2020.1760587.

Health, Center for Devices and Radiological. "Artificial Intelligence and Machine Learning in Software as a Medical Device." *FDA*, September 22, 2021. https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device.

Santos, Marcel Koenigkam, José Raniery Ferreira Júnior, Danilo Tadao Wada, Ariane Priscilla Magalhães Tenório, Marcello Henrique Nogueira Barbosa, and Paulo Mazzoncini de Azevedo Marques. "Artificial Intelligence, Machine Learning, Computer-Aided Diagnosis, and Radiomics: Advances in Imaging towards to Precision Medicine." *Radiologia Brasileira* 52, no. 6 (2019): 387–96. https://doi.org/10.1590/0100-3984.2019.0049.

Castellino, Ronald A. "Computer Aided Detection (CAD): An Overview." *Cancer Imaging* 5, no. 1 (August 23, 2005): 17–19. https://doi.org/10.1102/1470-7330.2005.0018.

"Computer-Aided Diagnosis in Medical Imaging: Historical Review, Current Status and Future Potential." Accessed November 9, 2021. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1955762/.

Kohli, Ajay, Vidur Mahajan, Kevin Seals, Ajit Kohli, and Saurabh Jha. "Concepts in U.S. Food and Drug Administration Regulation of Artificial Intelligence for Medical Imaging." *AJR. American Journal of Roentgenology* 213, no. 4 (October 2019): 886–88. https://doi.org/10.2214/AJR.18.20410.

Williamson, Ben. "Decoding ClassDojo: Psycho-Policy, Social-Emotional Learning and Persuasive Educational Technologies." *Learning, Media and Technology* 42, no. 4 (October 2, 2017): 440–53. https://doi.org/10.1080/17439884.2017.1278020.

Lan, Yu-Ju, Indy Y.T. Hsiao, and Mei-Feng Shih. "Effective Learning Design of Game-Based 3D Virtual Language Learning Environments for Special Education Students." *Journal of Educational Technology & Society* 21, no. 3 (2018): 213–27.

Dicheva, Darina, Christo Dichev, Gennady Agre, and Galia Angelova. “Gamification in Education: A Systematic Mapping Study.” *Journal of Educational Technology & Society* 18, no. 3 (2015): 75–88.

“How FDA Regulates Artificial Intelligence in Medical Products.” Accessed November 9, 2021. https://pew.org/3yglbCS.

El Mawas, Nour, Marilena Bratu, Dorothea Caraman, and Cristina Hava Muntean. “Investigating the Learning Impact of Game-Based Learning When Teaching Science to Children with Special Learning Needs.” In *30th Annual Conference of the Society for Information Technology and Teacher Education SITE*. Las Vegas, United States, 2019. https://hal.archives-ouvertes.fr/hal-02251329.

Gonçalves, Mariana Alpalhão. “LLM in Law & Technology Tilburg Law School Tilburg University August 2018,” n.d., 75.

mddionline.com. “New Developments in FDA Regulation of AI,” April 9, 2020. https://www.mddionline.com/regulatory-quality/new-developments-fda-regulation-ai.

Latour, Bruno. “On Actor-Network Theory: A Few Clarifications,” 1996, 369–81.

James, McKenzi. “The Impact of Game-Based Learning in a Special Education Classroom,” n.d., 21.